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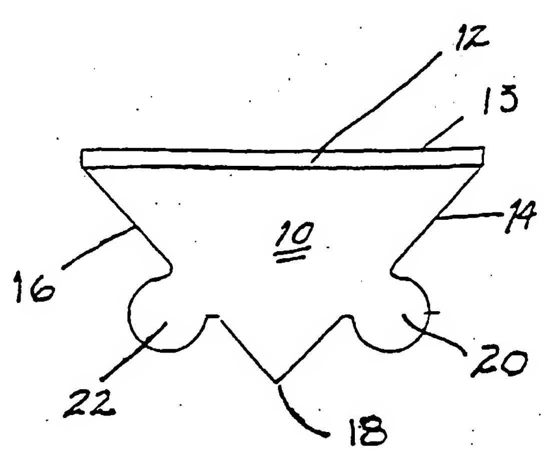
(54) Title: CUTTING BLADE AND CUTTING BLADE ASSEMBLY FOR OPHTHALMIC PROCEDURES



(57) Abstract: A blade and a blade assembly wherein the blade has a front, beveled, sharpened edge (13), two side edges (14, 16) meeting at a point (18) spaced from the front edge and at least one attachment structure (20, 22) extending outwardly from each side edge. A blade holder, which extends beyond the side edges and attachment structures of the blade, sits on a top surface of the blade and is attached to the blade by a portion thereof which receives the attachment structures. The holder has an opening in an exposed surface to receive an extension from a drive mechanism such that when the drive mechanism is activated the blade is caused to vibrate or oscillate. The blade is oscillated in a lateral fashion when driven by a rod rotating along a circular path.

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CUTTING BLADE AND CUTTING BLADE ASSEMBLY FOR OPHTHALMIC PROCEDURES

This application is based on Provisional Application 60/231,964 filed June 23, 2000. Applicant claims priority from the filing date of said Provisional Application.

Background of the Invention

The invention relates to a blade, and a holder for that blade, for use in a manual or automated surgical device used for cutting the cornea of the eye and particularly for forming a corneal flap. Several surgical devices are currently available for cutting corneal tissue or a circular flap in the cornea around the pupil of the eye. These devices, commonly referred to as microkeratomes, are placed on the cornea and held in place by suction applied to the periphery of the cornea. A disposable blade is placed into the device and the sharpened edge of the blade is advanced at a precise angle and a predetermined depth into the corneal tissue. The device then provides for a vibrating or oscillating motion to the blade and allows the blade to be moved in a circular, linear, or curvilinear path around the central axis of the microkeratome. This results in the cornea being cut to raise a thin circular layer of anterior cornea with the incision being from about 100 to 200 micron, in depth and about 10 mm in diameter. In a more recent procedure, referred to as LASIK surgery, the circular corneal incision is combined with laser sculpting of a portion of the cornea.

Several microkeratomes are shown in the patent literature. US Patent 5,624,456 covers a device offered by Bausch & Lomb, known as the Hansatome, and US Patent 6,051,009 is directed to blades specifically designed for use in the device shown in the '456 patent.

Other patents to microkeratomes of different designs are shown in US Patents 5,496,339 and 5,658,303 to Koepnick, US Patent 4,884,570 to Krumeich, US Patent 5,501,174 and 5,591,174 to Clark et al, US 5,342,378 to Giraud et al, US Patent 6,022,365 to Aufaure et al, US Patent 5,133,726 to Ruiz et al, and US Patent 4,662,370 to Hoffmann et al. All operate in generally the same manner and all require a disposable blade be inserted therein. However, each device requires a different shaped blade and/or blade with blade holder. Therefore, there is a value in having a disposable blade configuration, which may have varied dimensions, which can be assembled with a suitable blade holder for each different device, using the same assembly

techniques, so as to provide ease of manufacturing and uniformity of surgical outcome irrespective of the instrument into which the blade or blade assembly is placed.

Summary of the Invention

The invention comprises a blade and a blade assembly wherein the blade has a front, beveled, sharpened edge, and two side edges meeting at a point spaced from the front edge. At least one attachment structure extends from each side edge. A blade holder which extends beyond the side edges, sits on a top surface of the blade and is attached to the blade by a portion thereof which receives the attachment structure. The holder has an opening in an exposed surface to receive an extension from a drive mechanism such that when the drive mechanism is activated the blade is caused to vibrate of oscillate.

Description of the Figures

FIGURE 1 is bottom view of a blade incorporating features of the invention.

FIGURE 2 is a side view of a first embodiment of a blade assembly including the blade of Figure 1.

FIGURE 3 is a top view of the first embodiment of the blade assembly of Figure 2.

FIGURE 4 is a bottom view of the first embodiment of the blade assembly of Figure 2.

FIGURE 5 is a side view of a second embodiment of a blade assembly including the blade of Figure 1.

FIGURE 6 is a top view of the second embodiment of the blade assembly of Figure 5.

FIGURE 7 is a side view of a third embodiment of a blade assembly including the blade of Figure 1.

FIGURE 8 is a rear view of the third embodiment of the blade assembly of Figure 7.

FIGURE 9 is a bottom view of a variation of the assembled embodiment of Figure 4.

FIGURE 10 is a bottom view of the blade holder of the variation of Figure 9.

FIGURE 11 is a top view of the blade holder of the variation of Figure 9.

FIGURE 12 is a cutaway side view along line 220-220 of Figure 9.

FIGURE 13 is a top view of an alternative blade design having a parabolic shape.

FIGURE 14 is a bottom view of the blade of Figure 13 mounted in a blade holder.

FIGURE 15 is a top view of an alternative blade design with a semicircular shape having circular retention means within the periphery of the blade.

FIGURE 16 is a top view of a blade holder for receiving the blade of Figure 15.

Detailed Description of the Invention

Figure 1 shows a top view of a blade incorporating features of the invention. As shown in Figure 1, the blade 10, in a preferred embodiment fabricated of a flat surgical steel about 0.01 inches thick, is in the shape of a triangle with a forward portion 12 beveled to a sharp edge 13. The various triangular embodiments have a forward portion from about 0.45 to about 0.53 inches in width. The triangular blade has a dimension from the forward portion 12 to the point 18 from about 0.27 to about 0.32 inches. The two side edges 14, 16 of the blade meet at a point 18 spaced from the front edge 12. Extending from each of the side edges 14, 16 are extensions 20, 22, generally in the plane of the blade. In the embodiment shown in the figures, the extensions 20, 22 are circular in shape, the circular extensions intersecting the first and second side edges 14, 16 of the blade. In a preferred construction, the circular extension 20, 22 have at least about 180° of the circumference extending from the blade. Figures 1 and 9 have about 270° of the circumference in the extension while the remaining 90° constitutes the intersection of the extensions 20, 22 with the blade side edges 14, 16.

In order to adapt the various blades 10 to operate with the various different microkeratomes the blade is generally attached to a holder to form a blade assembly, the holder being designed to receive a drive mechanism. Figures 2, 3 and 4 show a side, top and bottom view of a first embodiment of the blade of Figure 1 attached to a blade holder 24 to form a blade assembly 26. The blade holder is typically formed of a machined or molded plastic material. As best shown in Figure 4 and the variation of Figure 10, the bottom surface 28 of the blade holder 24 has an indented blade receiving portion 25 with raised areas 27 on either side of the indented area sized and shaped to receive the extensions 20, 22 as well as a portion of the blade itself. A circular extension 20, 22 extending more than 180° in arc is preferred as this provides a self centering function when the blade is attached to the blade 24 holder by various assembly techniques. The blade 10 is retained in the indented blade receiving portion 25 in the blade holder 24 by an adhesive, cold staking, heat staking, over moldings, or snap (detent) fit means. Snap

(dent) fittings utilizes a receiving portion with an angled edges 60 as shown in Fig. 12. Alternatively, a preformed blade 10 may be molded into the plastic blade holder 24 when it is formed. Also, the bottom surface of the blade holder 24 is at an angle to the plane of the top surface, typically 10° to 45°, so that the blade rests at a desired angle to horizontal when placed in the microkeratome. Alternatively, a separate bottom (not shown) can be applied to the blade holder 24 to sandwich the blade 10 between the holder 24 and the bottom cover.

As shown in Figure 3, the blade holder 24 has a non-circular aperture 30 in the top thereof to receive a drive mechanism 50. Typically, as shown in several of the patents cited above and incorporated herein by reference, the drive mechanism 50 is a rod offset mounted on a rotating shaft. The rod has a diameter substantially the same as the width of the aperture 30. Rotation of the shaft causes the rod to rotate in a circular path, which in turn causes lateral oscillation of the blade assembly in the microkeratome. This oscillating motion is intended to improve the quality of the cut made by the sharp edge 13 of the blade 10. In this instance, the drive mechanism 50 enters the aperture 30 in a substantially vertical manner but at an angle to the plane of the blade. This embodiment is designed for use in a microtome manufactured by Bausch & Lomb and referred to as the HANSATOME ™.

Figures 5 and 6 are to a second embodiment of the blade assembly which incorporates the blade 10 of Figure 1 with a different designed blade holder 40 for use in the C-B™ microkeratome manufactured by Moria. This blade assembly also receives a substantially vertical drive mechanism 50. However, because the aperture 30 can be a slot or oval, the blade assembly can receive a drive mechanism 50 mounted in other than a vertical manner and still function in substantially the same manner.

Figures 7 and 8 show a third embodiment designed to receive a drive from other than the vertical. The drive 50 may in fact be parallel to the plane of the blade, as shown in some of the above referenced patents. In such an instance, the blade may be held in the keratome at an angle to the vertical, or horizontal. Like components are numbered the same as in the prior figures.

A variation of the blade of Figure 1 and the holder of Figure 2-4 is shown in Figures 9-11. In this variation the holder 24 has holes 44 therethrough. While the hole 44 has been shown as round, any shape hole can be used. The purpose of the hole 44 in the holder 24 is to assure

proper alignment of the holder 24 on a machining fixture (not shown) when the holder 24 is positioned or refixtured for the machining of the indented blade receiving portion 25. This assures proper location or registration of the blade with the slot 30 in the assembled product.

As shown in Figure 2 and 10, the blade holder 24 can also have a groove 46 therein so that one blade of a forceps or tweezer can be inserted therein to grasp the blade 10 for placement of the blade 10 with attached blade holder 24 in to the microkeratome.

While Figure 1 shows the extensions 20, 22 as circular pieces extending from the sides, the extensions can be of various different shapes designed to mate with a like shape in the holder. While shown to be in the plane of the blade 10, the extensions 20, 22 can also be at an angle to the plane or be perpendicular to the plane for insertion in matching holes extending into the holder. It is also contemplated that the blade may be fabricated from a material other than stainless steel, such as ceramics, zirconium, sapphire or similar material, or may have coatings on the beveled front edge to aid in creating a smooth cut in the corneal tissue. It is also possible for the blade and blade holder to be fabricated as a single piece with front edge treated to produce a suitable cutting surface or to receive a cutting component, such as a sapphire, or diamond, ceramic or zirconium, cutting edge, such as typically used in other ophthalmic tissue cutting tools. A typical material for construction of the blade holder is acetal (Delrin®), nylon or other engineering plastics which can be formed or machined into structures with dimensions having controlled tolerances. It is also possible that the holder and blade could be formed of a single engineering plastic capable of forming or being formed into a sharp forward blade edge. Still further, the whole assembly could be of a hard material, such as a ceramic material, which can be honed to a sharp edge.

Figure 13 -16 show additional embodiments of the blade. The overall shape of the blade 100 is parabolic with a front portion thereof removed to form a sharp front edge 13. The blade 100 is placed in a holder 124 fabricated with an indented portion for receiving the blade 100 with extensions 20, 22 in the manner as described in the regard to the embodiments described above.

As set forth above, the extensions 20, 22 can be of any shape. Also, if they are circular extensions, they preferably include at least about 180° of arc to provide a secure registration of the blade in the holder. The dimensions of the parabolic shape of the blade can be varied.

Still further, the blade shape does not have to be parabolic or circular but can be oval (elliptical) in shape or have a compound curved surface. It can also have more than two extensions.

Figure 14 shows the blade of Figure 13 in the blade holder 24.

A still further variant, shown in Figure 15, is a circular blade 130 with cut off front portion and, rather than circular extensions, circular incursions 120, 122 in the circumferential walls. Figure 16 is a holder designed to receive the blade of Figure 15. Instead of including a indented receiving portion as in the prior described embodiments, this blade shows an alternative holding mechanism which incorporates circular extensions 226 which are inserted in the blade incursions 120, 122 to secure the blade 130 to the blade holder 224. The attachment techniques discussed above can also be used.

We claim:

1. A blade assembly for use in a surgical device that cuts at least partially across the cornea of an eye of a patient, the surgical device including means attachable to the cutting blade assembly to cause a forward cutting edge of the blade assembly to vibrate or oscillate, the cutting blade assembly comprising:

a) a triangular shaped cutting blade comprising a forward portion constituting a first side of the triangular shaped cutting blade and first and second rearwardly extending side edges constituting a second and third side of the triangular shaped cutting blade, the front portion comprising a sharp, cutting edge in the plane of the blade and extending across the width thereof, the triangular shaped blade also including a first and a second extension projecting outwardly from the first and second side edges, respectively, and

b) a blade holder having a driving mechanism receiving portion and an blade receiving portion, the blade receiving portion sized and shaped to receive the triangular shaped blade and extensions with the sharp edge of the front portion extending beyond a front surface of the blade holder, the triangular blade being secured within the blade receiving portion of the blade holder.

2. The blade assembly of claim 1 wherein the blade receiving portion of the blade holder comprises an indented area on a face of the blade holder, the indented area being located between two spaced apart raised areas, the raised areas being located in contacting relationship with the first and second side edges of the cutting blade.

3. The blade assembly of claim 1 wherein the extensions on the blade are circular and have a circumference at least about 180° of a circle..

4. The blade assembly of claim 1 wherein the extensions on the blade project outwardly in the plane of the blade.

5. The blade assembly of claim 1 wherein the blade holder has registration means therein, for use in reproducible positioning in the blade holder for machining the blade holder and reproducibly placing the blade in the blade holder.

6. The blade assembly of claim 5 wherein the registration means in the blade holder comprises a hole in the blade holder shaped and sized to temporarily receive a like shaped and sized positioning in for machining.

7. The blade assembly of claim 1 wherein the blade is secured to the blade holder by a pressing the blade with extensions into the like-sized and shaped indentation in the face of the blade holder.

8. The blade assembly of claim 1 wherein the blade receiving portion has extended upper edges for snap fitting of the blade therein.

9. The blade assembly of claim 7 wherein the blade is further secured to the blade holder by an adhesive.

10. The blade assembly of claim 1 wherein the blade is secured to the blade holder by molding a preformed blade into the blade holder during formation of the blade holder.

11. The blade assembly of claim 1 wherein the blade holder includes a cutout portion on the face thereof for receiving a grasping portion of an instrument used to grasp the blade during placement into and removal of the blade and blade holder into a surgical instrument.

12. The blade assembly of claim 1 wherein the driving means receiving portion comprises an aperture in a second surface of the blade holder, said aperture being oriented to receive the driving means of the surgical device in a predesigned orientation to the plane of the blade.

13. The blade assembly of claim 12 wherein the second surface of the blade holder is 10° to 45° to a plane parallel to the plane of the blade.

14. The blade assembly of claim 12 wherein the second surface of the blade holder is 10° to 45° to a plane perpendicular, to the plane of the blade.

15. A blade assembly for use in a surgical device that cuts at least partially across the cornea of an eye of a patient, the surgical device including means attachable to the cutting blade assembly to cause a forward cutting edge of the blade assembly to vibrate or oscillate, the cutting blade assembly comprising:

a) a cutting blade having a straight forward portion constituting a first side and a rear portion constituting a circular shaped circumferential edge extending rearwardly, the front portion comprising a sharp cutting edge in the plane of the blade extending across the width thereof, the circular shaped blade having first and a second attachment means thereon or therein, and

b) a blade holder having a driving mechanism receiving portion and an blade receiving portion, the blade receiving portion sized and shaped to receive the circular shaped

blade with the sharp edge of the front portion extending beyond a front surface of the blade holder,

the circular shaped blade being secured within the blade receiving portion of the blade holder, the circumferential edge of the blade being configured to cooperate with blade holder to secure the blade and blade holder in a predetermined positional relationship.

16. The blade assembly of claim 15 wherein the blade has a first and a second extension projecting outwardly from the circumferential side edges, and the blade receiving portion of the blade holder has like shaped receiving portions therein.

17. The blade assembly of claim 16 wherein the first and a second extension projecting outwardly from the circumferential side edge are circular in shape.

18. The blade assembly of claim 15 wherein the blade has first and a second indentations through the circumferential side edges and the blade receiving portion of the blade holder has like shaped receiving extensions therein.

19. A blade for a microtome, the blade being circular or parabolic in shape and comprising

a) a straight front cutting edge,

b) a circumferential side edge extending rearwardly from left and right ends of the front cutting edge, and

c) first and second spaced apart extensions projecting outwardly in the plane of the blade from the circumferential side edge.

20. A blade for a microtome, the blade being circular in shape and comprising

a) a straight front cutting edge,

b) a circumferential side edge extending rearwardly from left and right ends of the front cutting edge, and

c) first and second spaced apart openings extending intwardly in the plane of the blade from the circumferential side edge.

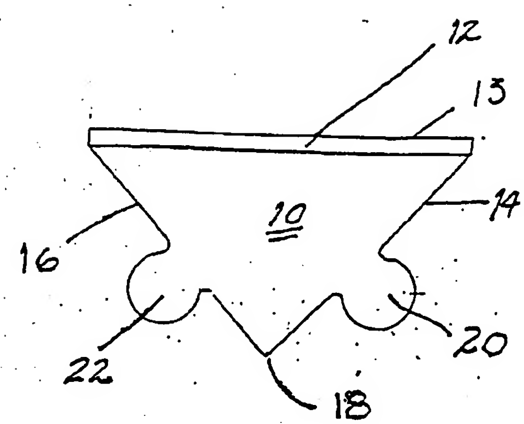

FIG 1

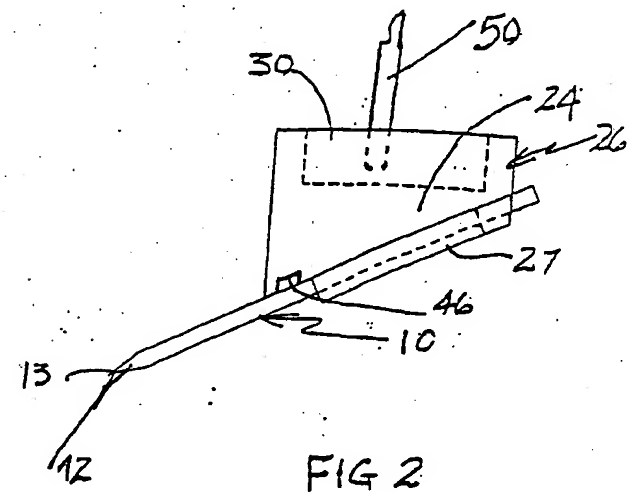

FIG 2

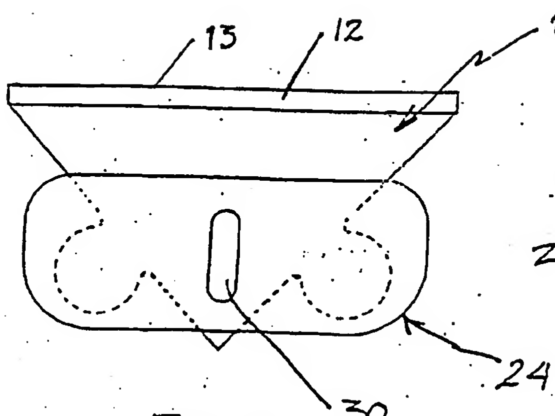

FIG 3

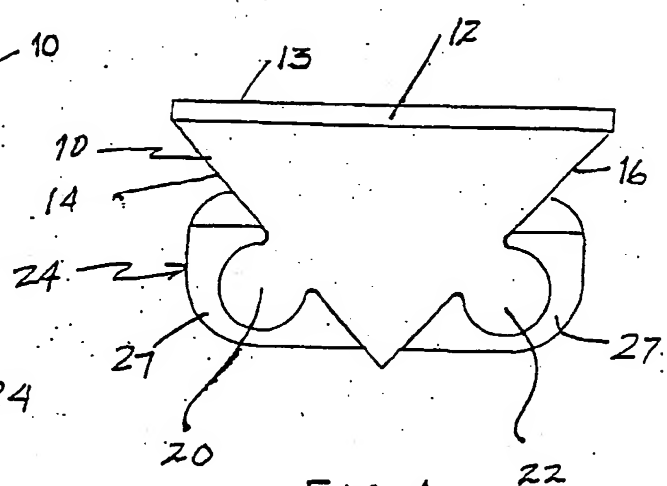

FIG 4

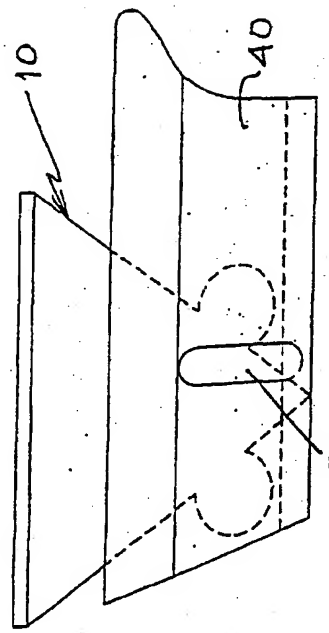

FIG 6

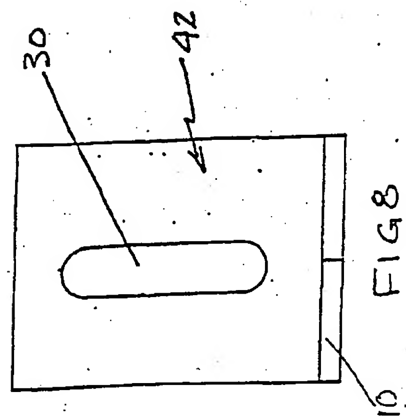

FIG 8

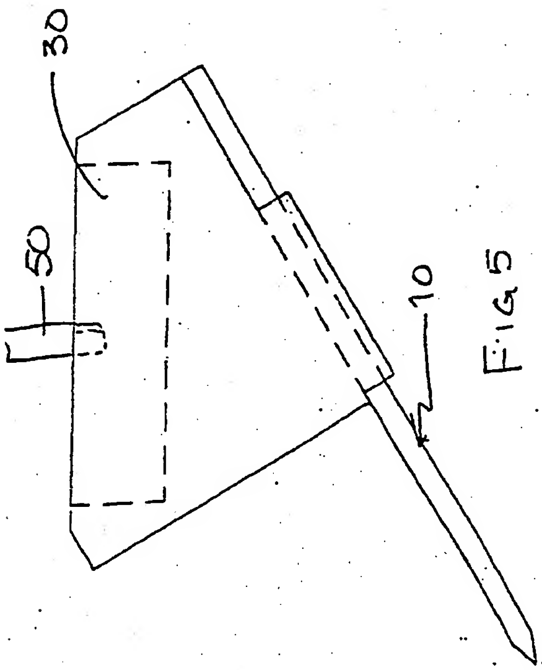

FIG 5

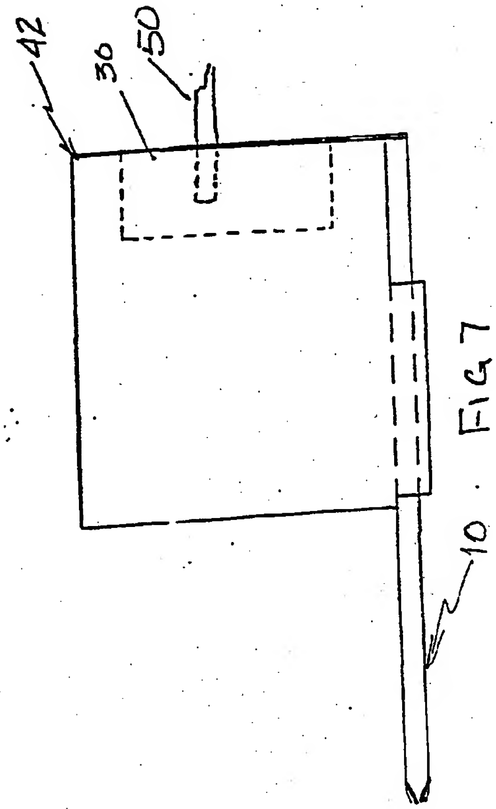

FIG 7

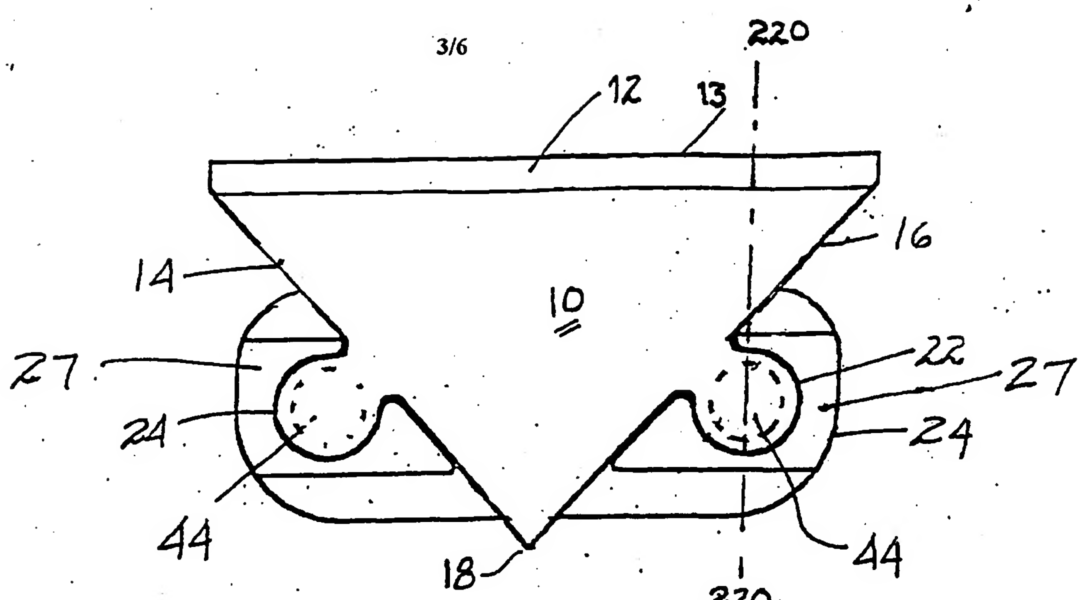

FIG 9

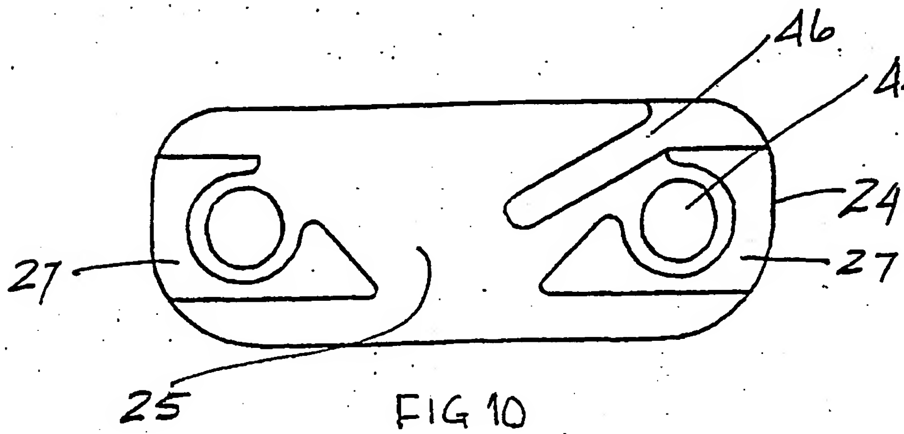

FIG 10

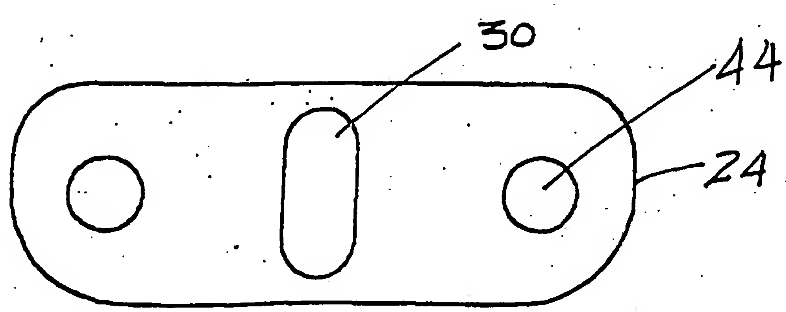

FIG 11

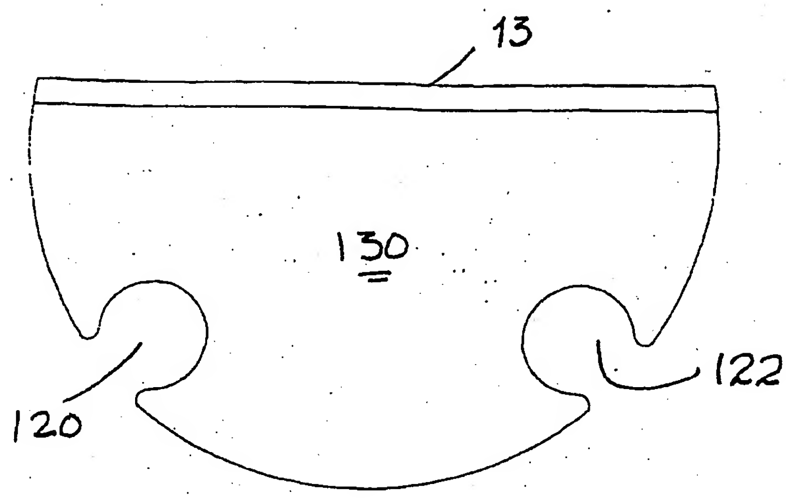

FIG. 15

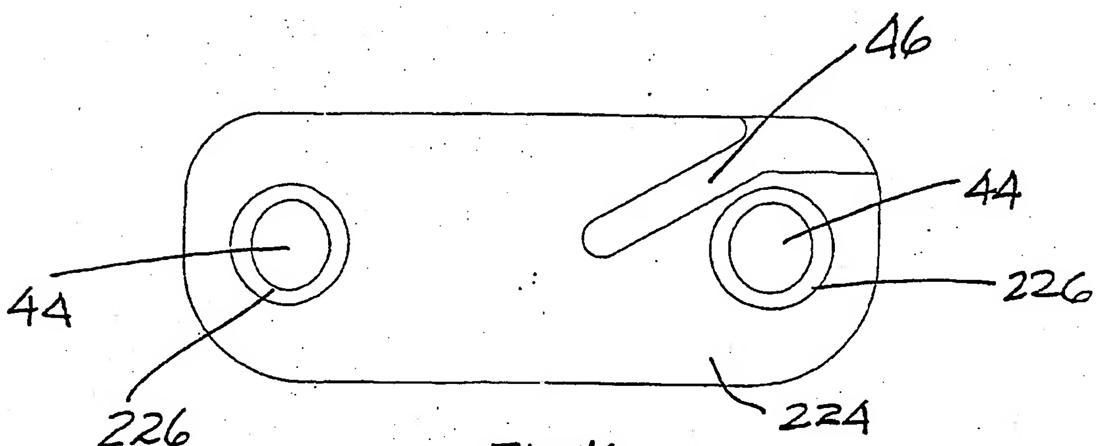

FIG.16

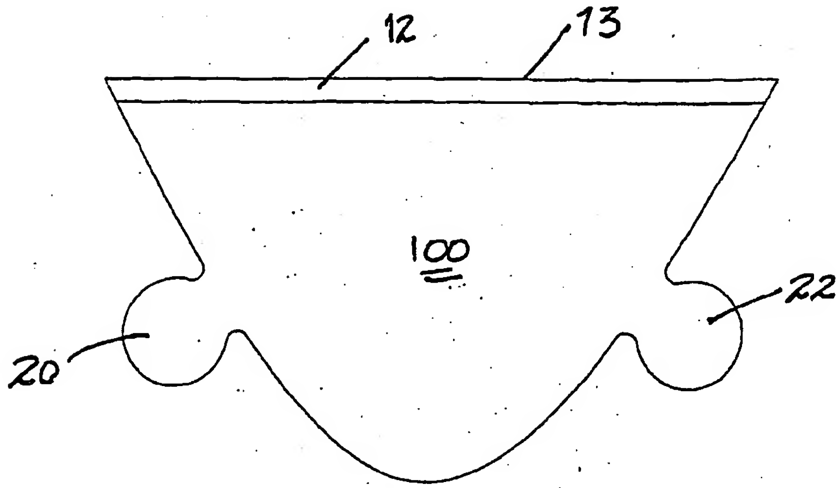

FIG.13

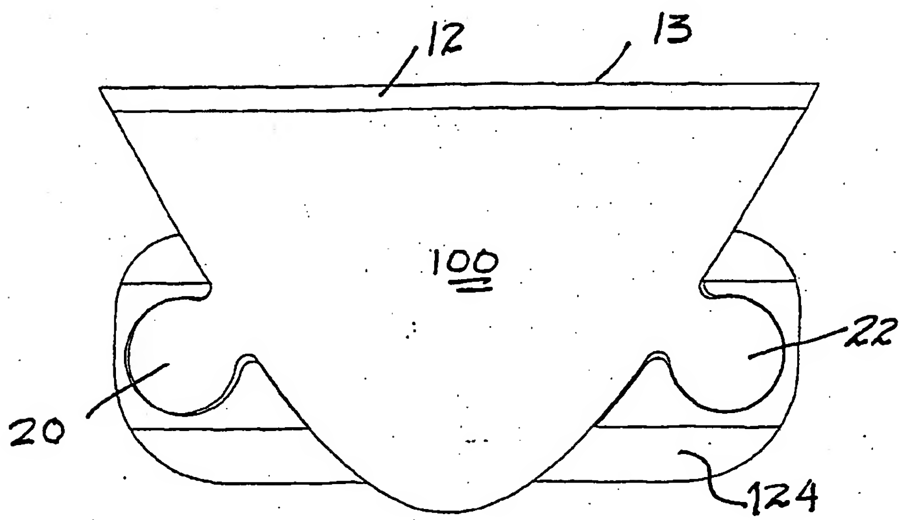

FIG. 14

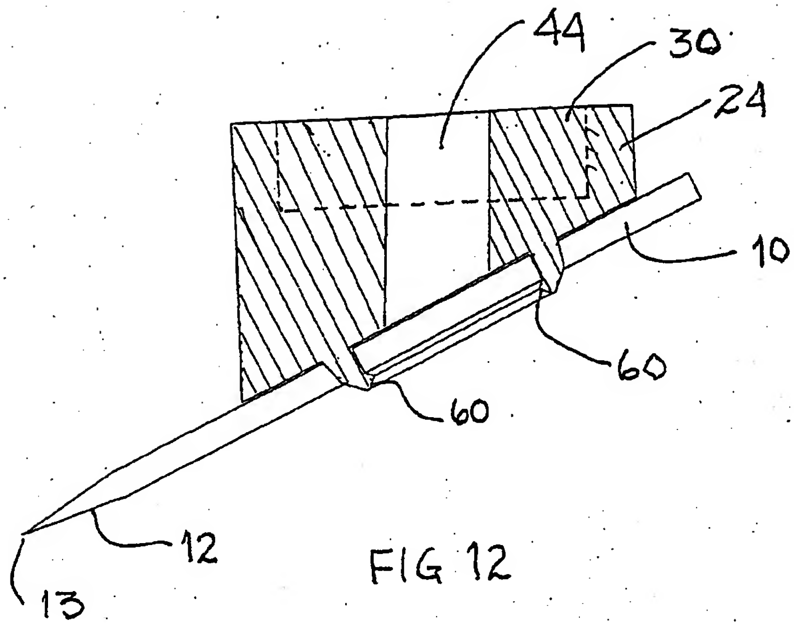

FIG 12

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/19611

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F9/013

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 26568 A (HAWKEN IND INC) 3 June 1999 (1999-06-03) page 16, line 13 - line 16; figure 4	1,15,19, 20
A	US 5 619 889 A (JONES GARY W ET AL) 15 April 1997 (1997-04-15) column 13, line 14 - line 20; figure 15	1,15,19, 20
A	US 6 051 009 A (HELLENKAMP JOHANN F ET AL) 18 April 2000 (2000-04-18) cited in the application column 11, line 36 - line 57; figures 6,7	1,15,19, 20

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
12 October 2001	22/10/2001

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT
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Interna: ;l Application No
PCT/US 01/19611

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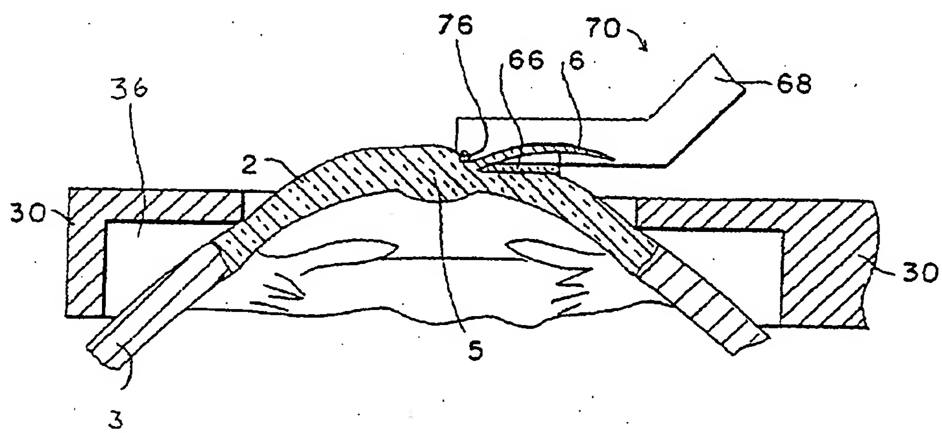

(57) Abstract: A keratome for performing corneal resectioning which functions without a need for a surface against which to press the subject cornea during surgery, facilitating access for the surgeon and reducing or eliminating mechanical part rubbing near the surgical site. The keratome has a positioning ring to position an eye with the cornea protruding through and restrained by the ring. A blade is preferably suspended from its ends by a blade support which is driven by a drive mechanism, and a guide is disposed substantially parallel to the blade. The blade describes a forward path above and at a controlled distance from the positioning ring while also oscillating laterally. A guide may be disposed parallel to the blade edge to control resectioning thickness. Drive control and vacuum for the positioning ring are provided under user command by a control unit having user inputs.

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"Keratome Without Applanator"

Field of the Invention

The present invention pertains to the general field of ophthalmologic surgical devices, and more specifically to the field of devices for performing corneal resectioning and methods therefor.

BACKGROUND

Numerous ophthalmic surgical procedures, such as for correcting myopia or hyperopia, require one or more steps of resectioning the cornea of the eye. A variety of devices called keratomes have been developed over recent decades to perform such corneal resectioning. Referring to Figs. 1, 2a and 2b, a typical resectioning operation will separate flap 6 of corneal tissue 2 from eyeball 4. The tougher outer layers of epithelial cells 8 are separated and lifted away to expose the more compliant inner layers 12 of cornea 2, but the separated outer layers are left attached as flap 6. Once exposed, interior layers 12 of cornea 2 will to some extent adjust themselves, or their shape may be altered through further surgical steps. Such further steps may include, for example, making radial keratotomy cuts or performing a subsequent resectioning which may include removing a contoured layer of corneal tissue. At the conclusion of the various steps of the surgical procedure, flap 6 is typically replaced over inner corneal tissues 12 to protect the healing tissues.

The representative keratomes described in U.S. patents 5,496,339 issued to Koepnick, and Re. 35,421 issued to Ruiz et al., which are depicted in Figs. 3a and 3b, demonstrate many standard features of prior art keratomes. A retaining ring for positioning and retaining the subject eyeball is typically supplied with a source of vacuum. The vacuum pressure draws the eyeball into the retaining ring so that the cornea protrudes through the retaining ring and presses against the surface of a feature, herein referred to as an applanation shoe, which is provided to restrain the protruding cornea. An applanation shoe has been found important in all known prior art.

However, an applanator impedes access to the eye under surgery. One approach to this problem is to make the applanator pivotable, or otherwise disengageable from contact with the eye, without a need to disengage the entire surgical apparatus from its positioning on the eye.

In order to resection the cornea, a cutting blade must be drawn through the corneal tissue, and both the thickness and the expanse of the corneal tissue which is cut must be carefully controlled. The separated portion of the cornea is typically left attached along one edge to form flap 6 which can easily be replaced over the cornea after the surgery.

Keratomes must have a mechanism by which the knife blade is guided. Proximate to the cutting location, the prior art keratomes all have blades rubbing on guides, or metal rubbing on metal, such as drive gears. Unfortunately, such rubbing can result in shavings being created and entering the surgical site. Referring to Fig. 3a, the keratome of Ruiz et al. has an intricate mechanism with metal-on-metal gears rubbing in the surgical vicinity. For example, pinion 834 rides on track 891 which is part of positioning ring 890; and endless pinion 822, along with its eccentric shaft and associated pinions, operates directly above the blade cutting site (not shown). In Fig. 3b, the keratome of Koepnick is seen to have blade 954 which rubs directly on the insert 948 and slides in surfaces defined along line 991. The sliding surfaces at 991 are located directly above positioning suction ring 990, and the rubbing surface between blade 954 and insert 948 is directly adjacent regions of intimate contact between the corneal tissue and insert 948. Thus, these two prior art keratome examples have rubbing between the cutting blade and other surfaces, and rubbing of gears, very close to the surgical site.

Another drawback of existing keratomes is the inconvenience of maintaining surgical cleanliness. Since parts of the keratome must be in intimate contact with tissues around and including the surgical site, it is necessary to ensure a high degree of cleanliness and sterility. The relatively intricate mechanisms which prior art keratomes position near the surgical site, as described above, have not been well-adapted for ease of cleaning and autoclaving.

Thus, a need exists for an easily used keratome able to perform precise resectioning operations, while facilitating surgical cleanliness by avoiding creation of shavings which might contaminate the surgical site, and by being easily cleaned, sterilized, and replaced.

SUMMARY OF THE INVENTION

A keratome in accordance with the present invention enables an ophthalmologic surgeon to perform corneal resectioning, separating a flap of corneal tissue for later replacement, without a need for an applanator, and without any rubbing of parts of the surgical device near the surgical site.

In accordance with the present invention, the surgical device preferably includes a surgical unit having cutting head elements mounted on a drive assembly, and also includes a control unit and a foot pedal. During surgery, the cutting head elements are in intimate contact with the subject eye, for positioning and cutting. The drive assembly element supports and drives the cutting head elements. The control unit is the preferred source of power and vacuum for the surgical unit, and it supplies power and vacuum according to settings entered by the user. The foot pedal allows the user to give commands to the surgical device without requiring use of hands. The surgical unit is preferably hand-held and easily positioned over the subject eye.

The preferred surgical unit includes three distinct elements. Two of these are "cutting head" elements which must contact the eye during corneal surgery -- a positioning ring assembly and a blade fork assembly. These two cutting head elements extend from the third element, a drive assembly, in such a way that interference and rubbing between the cutting head elements proximal to the surgical site is minimal or entirely absent. Preferably, the two cutting head elements are easily removed and as easily replaced onto the third element, the drive assembly, without a need for tools, so the surgeon can ensure sterility by simply attaching fresh and sterile replacements for the cutting head elements.

In a preferred embodiment of the present invention, a blade fork assembly suspends a cutting blade between the positioning ring and the applanation shoe and guides the cutting blade near to the applanation shoe. The thickness of the cut is preferably controlled by a guide, which is disposed a controlled distance away from the cutting blade. The outer layer of corneal tissue is separated by the blade as it passes between the blade and the guide, so that the thickness of the separated layer is controlled by the spacing between the blade and the guide.

The blade fork assembly is caused to move by the drive assembly, which imparts two distinct movements to the blade fork assembly during cutting action. One movement is a high-speed lateral oscillation, and the other, imparted at the same time, is a slow smooth forward movement. The drive arm impel the blade fork forward as long as it is commanded to do so through the control unit, until the drive arm impinges on an adjustable stop mechanism, thereby causing a clutch to slip and preventing further forward displacement of the drive arm.

The blade assembly is preferably entirely suspended and does not touch any part of the mechanism which is near to the surgical site except indirectly by way of the blade fork drive arm which supports the blade assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a cross-section of an eye.

Fig. 2a shows a cornea with a flap of epithelial tissue lifted.

Fig. 2b is a representation of the variation of corneal tissue beginning at the outermost layers.

Fig. 3a shows the prior art keratome of Ruiz et al.

Fig. 3b shows the prior art keratome of Koepnick.

Fig. 4 shows the control unit with connections to the surgical unit and to a foot pedal.

Fig. 5 shows the surgical unit, with the cutting head elements attached to the drive assembly.

Fig. 6 shows the drive assembly front end with the cutting head elements detached therefrom.

Fig. 7 shows an eye in a positioning ring and a blade cutting a corneal flap with thickness controlled by a guide.

Fig. 9a shows a blade fork assembly with a cam lever securing it to the blade fork drive arm.

Fig. 9b shows a blade fork assembly secured to the blade fork drive arm with a thumb screw.

Fig. 8a shows details of section 8a-8a of Fig. 9a, including the blade.

Fig. 8b shows details of section 8b-8b of Fig. 9b, including a stainless steel blade with guide.

Fig. 8c shows an alternative dual blade and guide in a section similar to 8b-8b.

Fig. 8d shows an alternative angled blade and guide in a section similar to 8b-8b.

Fig. 8e shows an alternative blade and bearing guide in a section similar to 8b-8b.

Fig. 10 shows the positioning ring releasably attached to the drive assembly.

Fig. 11 shows details of positioning ring restraint at section 11-11 of Fig. 10.

Fig. 12 shows a cross-section of a surgical unit using motor driven blade oscillation.

Fig. 13 shows alternative features for the surgical unit to permit field-driven blade oscillation.

DETAILED DESCRIPTION

The present invention is described below by examples which include the best mode known, but such description is not to be taken as limiting the invention, which is defined separately in the claims.

Referring to Figs. 4 & 5, the present invention is preferably embodied in three separate components: surgical unit 100, foot pedal 300, and control unit 400. Surgical unit 100 has three subsections including drive assembly 110 and two cutting head elements: positioning ring assembly 20 and blade fork assembly 60. Foot pedal 300 communicates user commands to control unit 400 via cable 310, and surgical unit 100 is connected to control unit 400 by electrical cable 410 and vacuum hose 412. Each of these items are discussed in more detail below.

CONTROL UNIT

The following describes a preferred embodiment of the invention with reference to Fig. 4. Control unit 400 is a microprocessor-controlled unit enabling the user to direct operation of the actuators within drive assembly 110 and the level of vacuum supplied to positioning ring assembly 20 of surgical unit 100. The user controls operation by means of two pedal switches of foot pedal 300, in conjunction with three rotary input devices 450, 452 and 454 and two pushbuttons 456 and 458 on the front panel of control unit 400. Operating parameters are displayed on the front panel for the user by means of numeric readouts 412, 414 and 416 and by multiple character alpha-numeric display 440, while speaker 434 gives audible information.

A microprocessor on printed circuit board 460 executes operating firmware which is held in reprogrammable non-volatile memory and can be reprogrammed in the field. The firmware allows the microprocessor system to read switch closures and the rotation of the rotary controls. These electronics translate operator actions into tool control voltages which are applied to the drive unit actuators and can be stored as presets to be recalled as required by the operator. The microprocessor system also interprets the sensors and controls the actuators to maintain vacuum at a level set by the user.

Control unit 400 provides electric control signals to surgical unit 100 via cable 410. Vacuum pressure for positioning ring assembly 20 is supplied from control unit 400 via vacuum hose 412. Control unit 400 contains vacuum reservoir 422 in which vacuum pressure is established by vacuum pump 420 and released by vacuum release solenoid 426, and the vacuum pressure is sensed by vacuum transducer 424 to give feedback to the control electronics. Electric control for the actuators (not shown) within drive assembly 110 is provided by electronic switches 436-438. Persons skilled in the art will appreciate that there is no limit to the variations by which control unit components may control the surgical unit actuators and vacuum.

SURGICAL UNIT

Referring to Fig. 5, surgical unit 100 includes drive assembly 110 for supporting and driving the cutting head elements which contact the eye during surgery, including positioning ring assembly 20 and blade fork assembly 60. Surgical unit 100 is supplied electrically via cable 410, and vacuum is supplied to positioning ring 30 via vacuum hose 412 which attaches to vacuum connection tube 22. Blade 66 will cut the corneal tissue in a flap of a thickness controlled by the spacing from blade 66 to guide 76.

Fig. 6 more clearly delineates the cutting head elements, positioning ring assembly 20 and blade fork assembly 60, as they are separated from front end 112 of drive assembly 110 without a need for tools. Since the cutting head elements ordinarily come into direct contact with a subject eye, it is preferable that they be removable and replaceable on drive assembly 110 without a need for tools, in order to facilitate the use of clean and sterile elements. For the same reason, it is also preferable that these cutting head elements be either sterilizable or sterile disposable.

Positioning ring support 32 preferably has tapered edges to mate with receiving feature 106 in drive assembly 110, with retention feature 34 also mating to a feature (not shown) of drive assembly 110. Positioning ring 30 may be restrained by thumbscrew 114. Blade fork 70 mates to drive arm 140, preferably using spring loaded ball detent assemblies 64 having a spring-loaded ball 62 to mate to drive arm notch 141. The three elements 20, 60 and 110 of surgical unit 100 are each described in more detail below.

Surgical Cutting Action

Fig. 7 shows the cutting head elements resectioning cornea 2. Vacuum pressure delivered to vacuum chamber 36 of positioning ring 30 will draw sclera 3 and cornea 2 of eye 4 upward to a stable position. Blade fork drive arm 140 (Fig. 5) supports blade fork 70 and imparts a compound movement to it. Blade fork 70 is oscillated rapidly in a direction parallel to the cutting edge of blade 66 (in and out of the page of Fig. 7), and simultaneously moved slowly forward (from right to left in Fig. 7), while maintaining blade 66 at a controlled distance from positioning ring 30. Blade 66, suspended from blade fork tines 68 along with guide 76, thereby separates a layer of corneal tissue 2 to form flap 6. The thickness of flap 6 is determined primarily by the spacing between blade 66 and guide 76, and to some extent by the guide and blade orientation and position. The forward travel of blade fork 70 continues until the formation of flap 6 is completed.

Blade Fork Assembly

Fig. 6 shows some details of blade fork assembly 60. A typical blade 66 and a representative guide 76 are shown suspended from blade fork tines 68. Optional spring detent insert 64 and the detent ball 62 of another spring detent insert are also shown. The detent ball of insert 64 will nest in notch 141 to releasably position blade fork 70 with respect to fork drive arm 140.

Fig. 9a shows blade fork assembly 60 suspending blade 66 and guide 76 from blade fork tines 68. Blade 66 and guide 76 are shown in cross section 8a-8a in Fig. 8a, and variations of the blade and guide arrangement are shown in Figs. 8b, 8c, 8d, and 8e. In Fig. 9a, blade fork 70 is attached to drive arm 140 using a trapezoidal mating construction, and the trapezoidal attachment between blade fork 70 and drive arm 140 is secured using a locking lever 144 which actuates a locking cam (not shown) by rotating about pivot 146.

Fig. 9b shows blade fork assembly 60 alternatively secured to blade fork drive arm 140 by thumbscrew 142. Spring loaded ball detent assembly 64 helps establish and hold the positioning of blade fork 70 with respect to drive arm 140. As above, fork tines 68 suspend blade 66 and guide 76, which can be seen in cross section 8b-8b in Fig. 8b. Figs. 8a, 8c, 8d and 8e show alternative examples of blade and guide arrangements which may be used.

Blade fork 70 is preferably composed of titanium but many other materials are

suitable, including stainless steel. For a steam sterilizable blade fork, dimensionally stable plastics such as polycarbonate or polysulfone are suitable, and gas or gamma ray sterilization is compatible with additional plastics, such as polypropylene.

Blade 66 is preferably sapphire or similar crystalline materials, which is hard and strong and desirably transparent for the best visibility as the cutting operation progresses. Alternatively, and particularly for disposable versions, the blade may be surgical stainless steel or other suitable material.

The overall position of blade 66 and guide 76 with respect to positioning ring 30 is established by the combined positioning of blade 66 and guide 76 in blade fork assembly 60, by the relative positioning of drive arm 140 to positioning ring mounting features 106 (Fig. 6), and by the positioning ring 30 dimensions. However, this is a less critical relationship than in many keratomes, because the relationship between blade 66 and guide 76 primarily determines the corneal flap thickness.

Fig. 8a shows details of section 8a-8a of Fig. 9a, including guide 76 disposed parallel to blade 66. The spacing between guide 76 and blade 66 controls the thickness of corneal tissue cut, enabling the cut thickness to be controlled very precisely and also to be set under controlled conditions at the factory. Guide 76 has a cross-section defined in a plane perpendicular to the longitudinal axis of blade 66.

The perimeter of the cross-section of guide 76 is advantageously small, preferably less than 2 mm or less than 6 mm. A small cross-sectional perimeter conveys several advantages: it reduces the frictional interaction between the guide and the cornea, it localizes a deformation 5 (Fig. 7) of the cornea to avoid pressure on the eye generally, and it reduces the likelihood of trapped bubbles distorting the cornea to cause inaccurate cuts.

Fig. 8b shows section 8b-8b, an arrangement of blade and guide for the blade fork assembly 60 shown in Fig. 9a. The leading edge of guide 76 is positioned very slightly forward (in the direction that the cutting head elements extend from the drive assembly) of the cutting edge of blade 66. Dimension x1 is the distance in the direction of blade travel between the leading edge of blade 66 and the leading edge of guide 76. The optimum length of dimension x1 depends on the orientations of the plane of blade 66 and, if applicable, of guide 76. Dimension x1 is preferably greater than zero, for example 0.20 +/- 0.05 mm or 0.30 +/- 0.05 mm. Dimension y1, the distance between guide 76 and blade 66 in a direction

perpendicular to the travel plane of blade 66, will vary depending upon the surgeon's needs, but will typically be made nominally 0.150 mm, 0.160 mm, 0.170 mm, or 0.180 mm, each nominal dimension being controlled to within a tolerance of preferably 0.030 mm or even more preferably 0.015 mm.

Fig. 8c shows, in a cross section similar to that of 8a-8a (Fig. 9a), an arrangement of blades 66 and 67 which may be suspended from blade fork tines 68. Here, lower blade 66 utilizes upper blade 67 as a guide for one flap of corneal tissue, while upper blade 67 utilizes guide 76 to control the thickness of a second flap of corneal tissue. Using this arrangement, a slice of corneal tissue of precise dimensions may be separated and then removed to accommodate an implant, leaving another flap 6 of the harder outer corneal tissue to cover the surgical site.

In Fig. 8d, blade 66 is shown having a small angle to the direction of travel, the angle preferably being about 25 degrees. Blade 66 is captured by screw 72 and washer 74, or suitable fastener. Flap thickness is controlled by the spacing from blade 66 to guide 76.

Fig. 8e differs from Fig. 8d in that guide 76 comprises central core 75 and outer cylindrical bearing 77, which is preferably made of a tough, low friction material such as a plastic containing TEFLON (TM) material. If bearing 77 is shorter than guide core 76 by an amount equal to the maximum lateral oscillation amplitude of the blade assembly, then with this arrangement bearing 77 may slide very little, or not at all, on the corneal tissue. Rather, sliding may occur at the interface between core 76 and bearing 77, and bearing 77 may only roll on the corneal tissue.

<u>Positioning Ring Assembly</u>

Fig. 6 shows positioning ring assembly 20, including positioning ring 30, vacuum connection nipple 24, vacuum tube stop 26, and vacuum connection tube 22. These items supply vacuum to assembly 20 to draw a subject eye into position and restrain it.

Figs. 10 and 11 depicts details of positioning ring assembly 20. Positioning ring 30 is provided with vacuum to vacuum chamber 36 so that an eyeball placed against it may be drawn in and restrained. The vacuum is furnished through vacuum connection tube 22, with the vacuum hose (not shown) placed over vacuum connection nipple 24 and stopped by vacuum tube stop 26. Alternatively, vacuum could be ducted through ring support 32 and

drive assembly 110 to obviate vacuum connection tube 22, with the vacuum hose in that case connected only to drive assembly 110 at any convenient location, such as adjacent to or even within control hose 410 (Fig. 5).

Referring to Fig. 10, which is a bottom view, and cross-section Fig. 11, positioning ring support 32 preferably includes retention feature 34 having detent 35. Retention feature 34 slides into matching recess 120 in drive assembly 110. Captured ball 117 settles into detent 35 under the pressure of captured spring 115 to properly locate positioning ring assembly 20. Then, thumbscrew 118 secures retention feature 34, seating it firmly against the sides of recess 120 formed in head 112 of drive assembly 110. Alternatively, thumbscrew 114 (e.g. Fig. 5) may be used from the opposite side of drive unit head 112 to secure positioning ring assembly 20.

As discussed with regard to blade fork assembly 60, a variety of materials may be used for positioning ring 20. The choice depends on whether sterility is to be ensured by reuse of the element in conjunction with a sterilization method, or by using sterile disposable elements. Suitable materials include metals, such as stainless steel, and plastics, such as polycarbonate, polysulfone, polypropylene or others.

Drive Assembly

Figs. 12 & 13 show details of a preferred embodiment for surgical unit 100, and in particular shows details of a preferred embodiment for drive assembly 110, which is largely enclosed by drive assembly cover 160.

Referring to Fig. 12, the primary actuators within drive assembly 110 are travel motor 180 and oscillation motor 170. Travel motor 180 drives shaft 184 through gear train 182. Clutch 190 couples a limited torque to screw 192. The rotational motion of screw 192 is converted to linear motion by threaded traveller 194. Pivot assembly 196 couples the motion from the forward end of traveller 194 to blade fork drive arm 140, while permitting drive arm 140 to oscillate rotationally about the pivot of pivot assembly 196. Blade travel stop adjust knob 150 preferably rotates a threaded member which adjustably stops blade fork drive arm 140 travel.

Drive arm 140 preferably includes portions of its top and bottom surface which are made closely parallel to each other and a controlled distance apart (the top and bottom

surfaces are those most distal from the center of drive arm 140 in the direction parallel to the pivot axis of pivot assembly 196, with the top surface being the farther from positioning ring 30). Drive arm 140 top and bottom surfaces are preferably flat to within .005 mm over their travel range of 1.5 cm, and are slidably captured by bearing surfaces 136 and 138 of drive assembly head 112. The bearing surfaces limit top-to-bottom play of drive arm 140 to preferably 0.01 mm or even more preferably to 0.05 mm.

Drive assembly head 112 holds positioning ring assembly 20 and blade fork drive arm 140 such that blade fork assembly 60 is maintained a known distance away from positioning ring 30 as the blade fork travels. The distance between blade 66 and applanation shoe 50 is preferably controlled to within +/- 0.5 mm, or more preferably within +/- 0.25 mm.

Oscillation is imparted to drive arm 140 by slider 176 which oscillates in a direction perpendicular to the page. Slider 176 interferes with the edges of a groove in drive arm 140, while the groove allows drive arm 140 to travel in and out of drive assembly 110. Slider 176 receives oscillation drive from oscillation motor 170 via shaft 172 and eccentric pin 174. Eccentric pin 174 rides in a slot in slider 176 which absorbs the vertical component of eccentric pin 174, but transmits the lateral motion.

ALTERNATIVE EMBODIMENTS OF THE INVENTION

It will be appreciated by those skilled in the art that many alternative embodiments are envisioned within the scope of the present invention. Some possible variations of the blade fork assembly are discussed in the blade fork assembly section above. Variations of other parts are discussed below, but do not represent an exhaustive survey of possibilities; rather, they serve as examples to show that a wide variety of mechanisms are encompassed within the scope of the invention.

Fig. 13 shows an alternative embodiment of means to impart oscillating motion to drive arm 140. In this embodiment drive arm 140 incorporates ferromagnetic material 144 which is acted on by magnetic fields generated by coils 175 positioned along the sides of drive arm 140.

Myriad physical configurations of the connection interface surfaces which removably attach the blade fork assembly to the blade fork drive arm can provide the predictable positioning needed to practice the invention. The mating parts of the interface are described

herein as trapezoidal or "dove-tail" but may take any form having locating features, including sawtooth, rectangular, eccentric oval, keyhole, or other shapes too numerous to enumerate.

Similarly, the means for securing the connection interface is shown herein as either a thumbscrew or a cam locking lever, but could be accomplished many other ways. To mention just a few examples, the mating parts could use magnetic attraction, spring-loaded detents, or tapered engaging pieces fitted into a recess formed partly from each of the mating parts. The mating pieces could even interfere snugly under normal conditions, and have a means to temporarily change the shape of one of the pieces to release the interference and thereby permit connecting or separating the interface. Any method known in the art to disengageably secure two pieces in a closely predictable relationship could be used.

Any blade fork can be used which is able to suspend the blade, and the guide if used, in a properly controlled position with respect to the mounting surface of the connection interface. The blade and the guide may take a multitude of shapes and comprise a multitude of materials; only a few such alternatives are discussed herein.

A preferred embodiment of this invention includes sterile disposable or sterilizable disposable cutting head elements. A non-limiting variety of material choices suitable for such an embodiment is discussed above with respect to each cutting head element. There is no need for the various cutting head elements to be all disposable or all permanent, but a mixture of disposable and sterilizable types is also suitable.

Surgical unit actuators may be driven by any known method, including pneumatic drive methods.

User commands may be recognized in any known way, including voice command reception, and sensing user activation of sensors or switches located on the surgical unit or in other convenient places. The commands thus recognized may exert control through any combination of control elements, which may include mechanical means, direct electrical control, or intelligent electrical control with intelligence provided by any means known to the art. The command recognition and control elements could be physically located amy accessible place, and as an example could be placed largely or entirely within the surgical unit.

CLAIMS

What is claimed is:

1. A surgical device for performing corneal resectioning, comprising:

a positioning ring to position and retain an eye, the positioning ring having an opening for a cornea of the eyeball to protrude therethrough;

a blade assembly including a blade and a guide; and

a drive mechanism to drive the blade assembly with respect to the positioning ring such that a cornea protruding through the opening of the positioning ring presses against the guide while the drive mechanism impels the blade assembly to move the blade through corneal tissue;

wherein a surface of the cornea protruding through the positioning ring is externally restrained only by the blade assembly.

2. The surgical device of claim 1 wherein the guide is in substantially fixed relationship to the blade.

3. The surgical device of claim 1 wherein the guide is disposed at a constant distance from the blade cutting edge, the guide having a cross-sectional area defined in a plane perpendicular to a blade longitudinal axis, the cross-sectional area having a perimeter.

4. The surgical device of claim 3 wherein the perimeter of the guide is less than 6 mm.

5. The surgical device of claim 1 wherein the blade is a first blade, further comprising a second blade in substantially fixed spatial relationship to said first blade and said guide.

6. The surgical device of claim 2 wherein the guide includes a core oriented parallel to the blade longitudinal axis and a bearing sheath annular to the core and rotatable thereabout.

7. The surgical device of claim 1 wherein the blade assembly is removeably secured and is readily removable without tools.

8. A blade assembly for use in a surgical device according to claim 7.

9. The surgical device of claim 1 wherein the positioning ring is removeably secured and is readily removable and replaceable without tools.

10. A positioning ring for use in a surgical device according to claim 9.

11. A method for performing corneal resectioning, comprising the steps of:

positioning an eye in a positioning ring having an opening for a cornea of the eyeball to protrude therethrough;

attaching a blade assembly having a blade and a guide to a drive mechanism connected to the positioning ring; and

controlling the drive mechanism to drive the blade assembly with respect to the positioning ring whereby to at least partially separate a flap from the corneal tissue protruding through the positioning ring, the flap having a thickness substantially controlled by a spacing and orientation between the blade and the guide, without concurrently restraining the protruding cornea externally by other than the blade assembly.

12. The method of claim 11 wherein the guide is in substantially fixed relationship to the blade.

13. The method of claim 11 wherein the blade is a first blade and the blade assembly includes a second blade in substantially fixed spatial relationship to said first blade and said guide.

14. The method of claim 11 wherein the guide includes a core oriented parallel to the blade longitudinal axis and a bearing sheath annular to the core and rotatable thereabout.

15. The method of claim 11 wherein the blade assembly has been removed, and including the further steps of securing the blade assembly without tools.

16. A method of assisting corneal resectioning comprising the step of supplying a blade assembly for use in the corneal resectioning method of claim 11.

17. The method of claim 11 including the further step of removeably securing the positioning ring without tools.

18. A method of assisting corneal resectioning comprising the step of supplying a positioning ring for use in the corneal resectioning method of claim 11.

19. The method of claim 16 including the step of supplying a disposable blade assembly.

20. The surgical device of claim 2 wherein the blade cutting edge is sapphire.

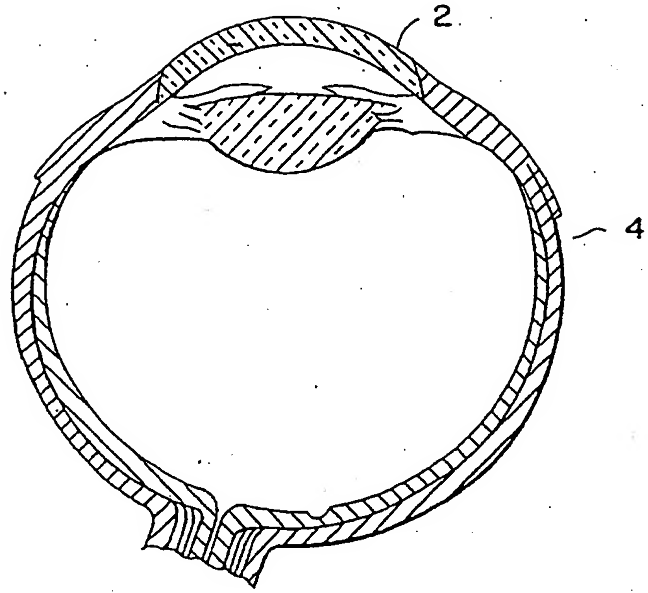
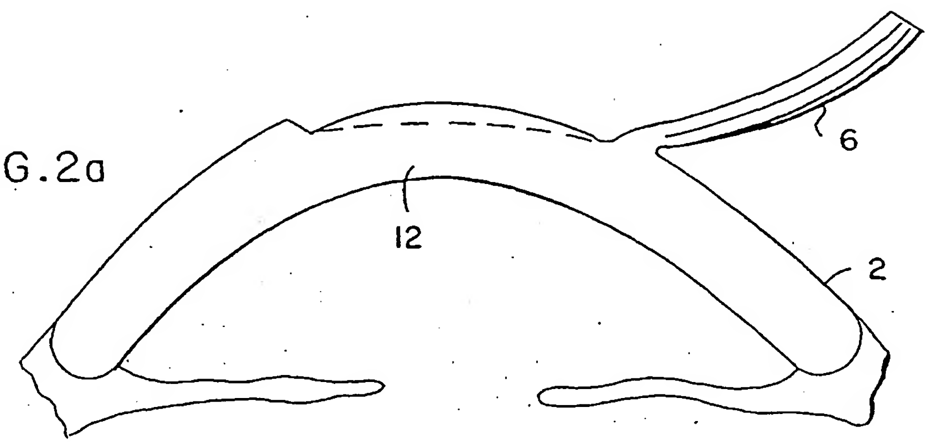


FIG. 1

FIG. 2a



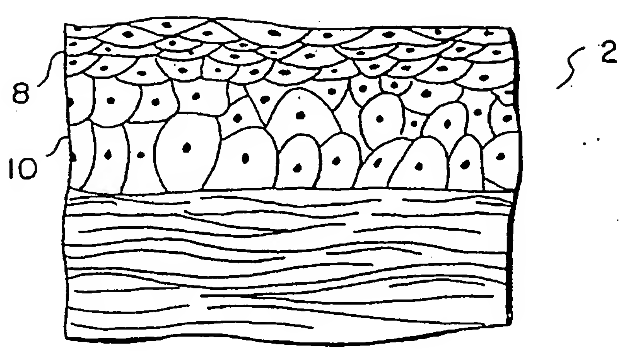


FIG. 2b

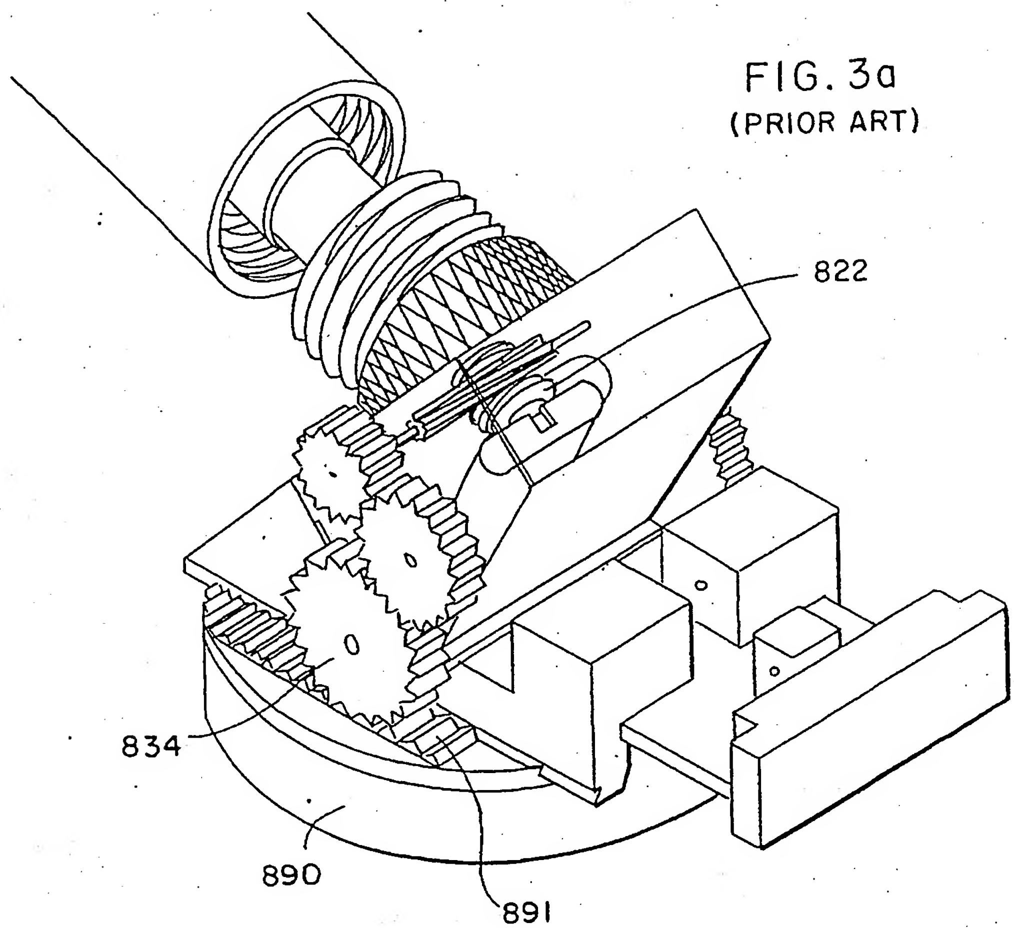


FIG. 3a
(PRIOR ART)

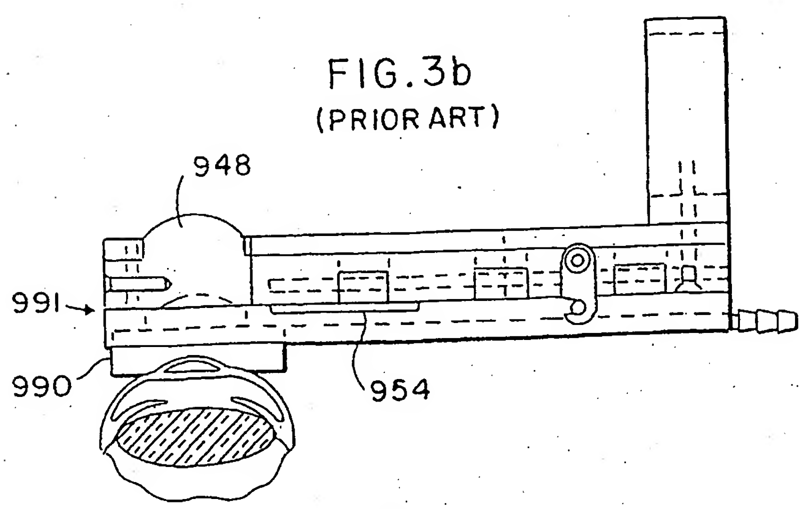


FIG. 3b
(PRIOR ART)

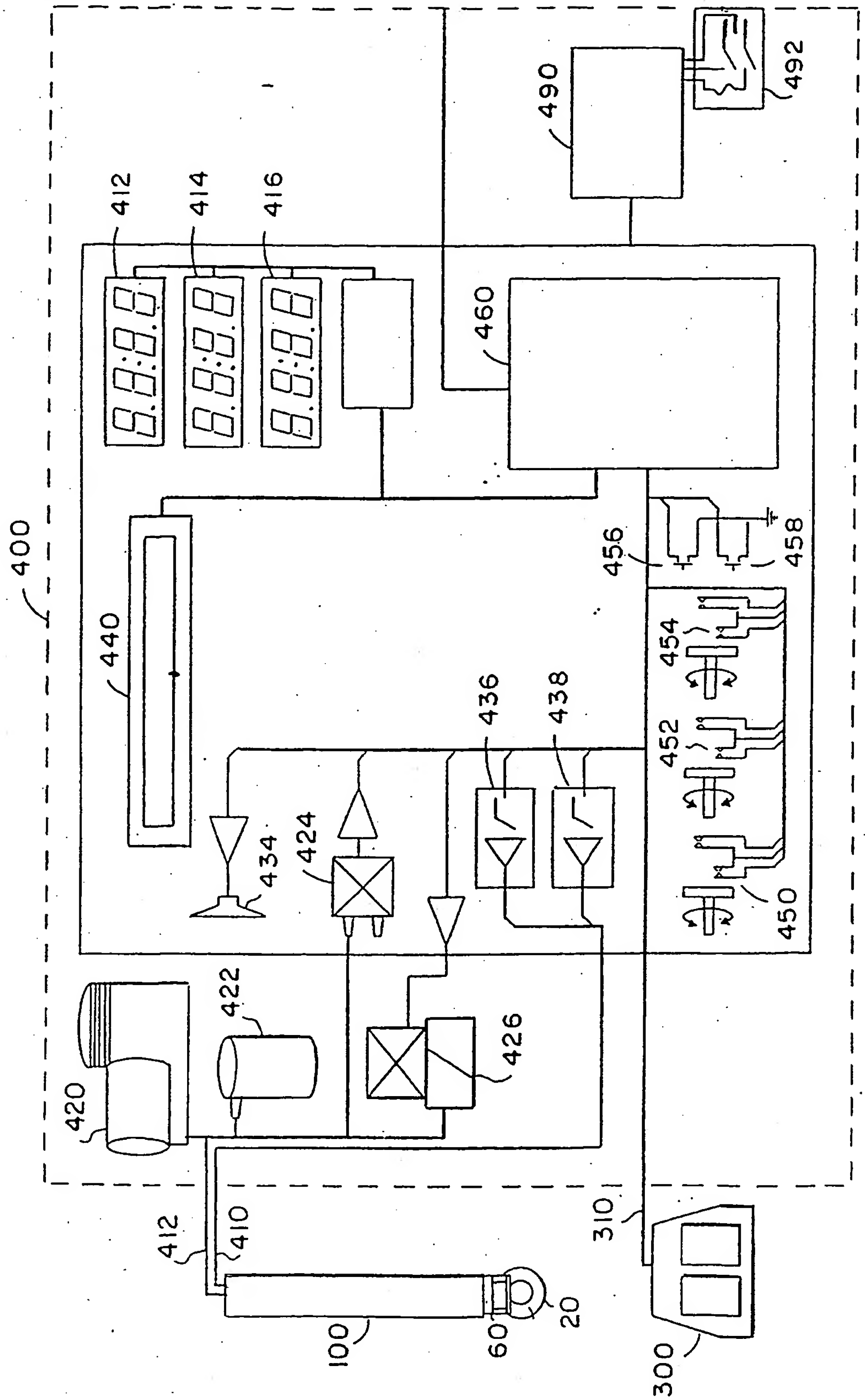

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FIG. 4

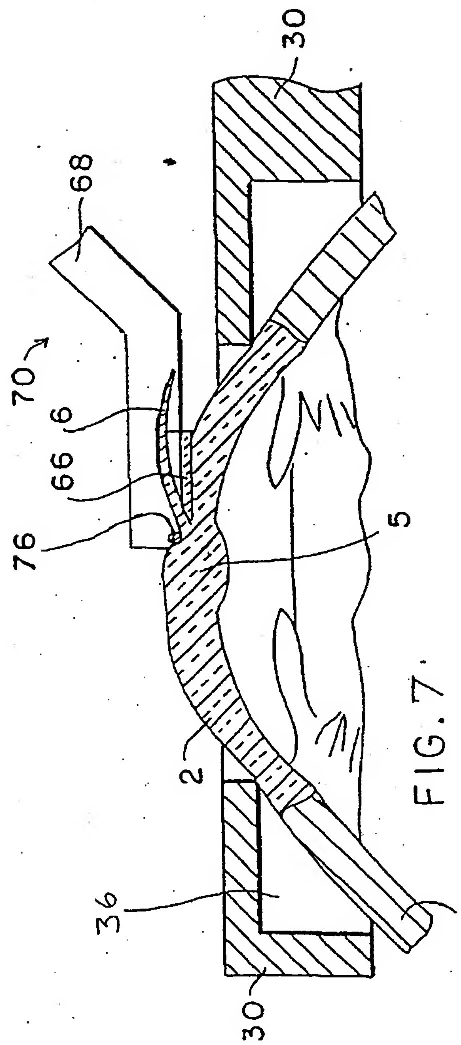
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FIG. 7

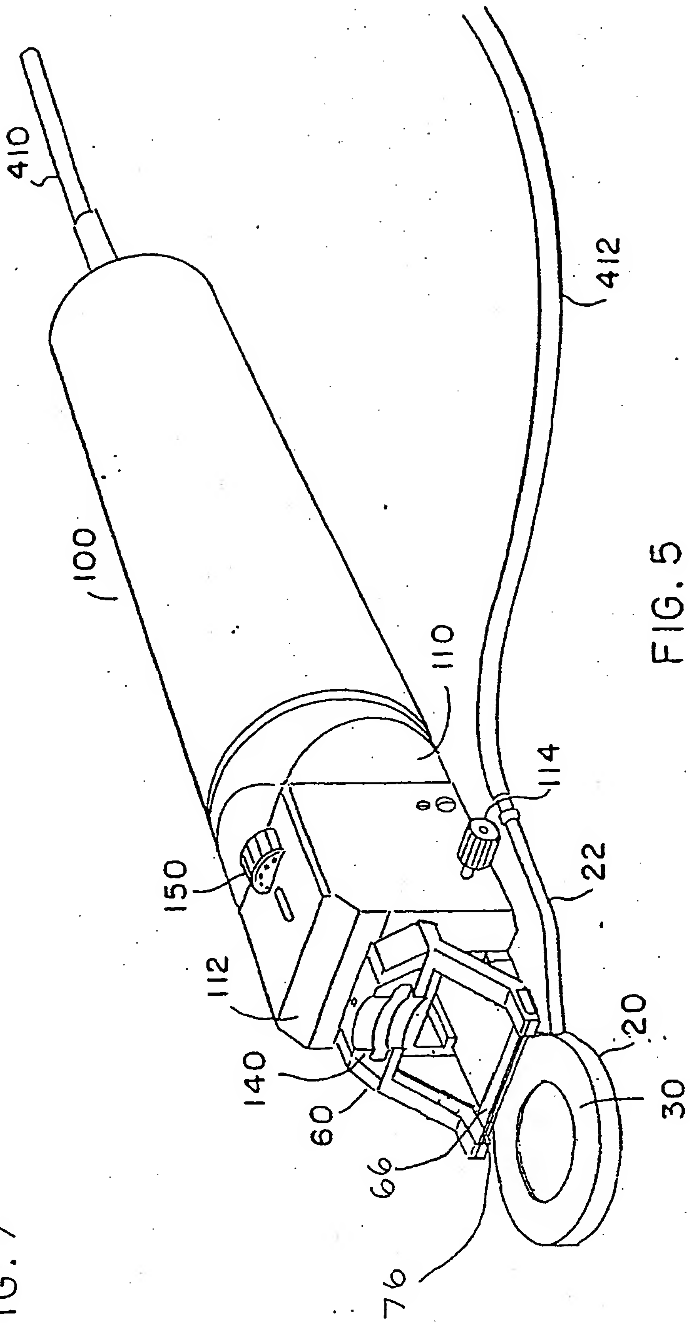
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FIG. 5

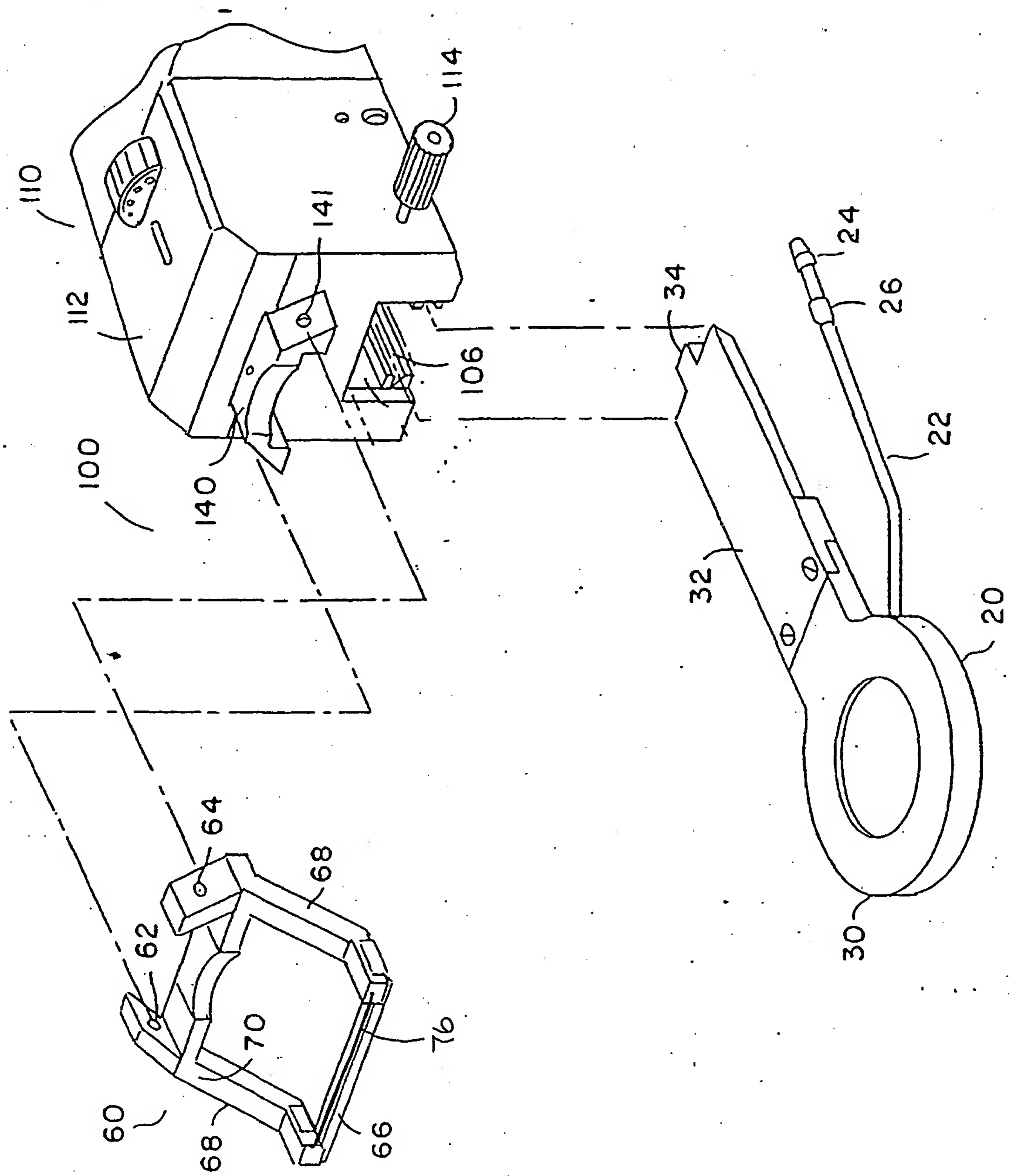
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FIG. 6

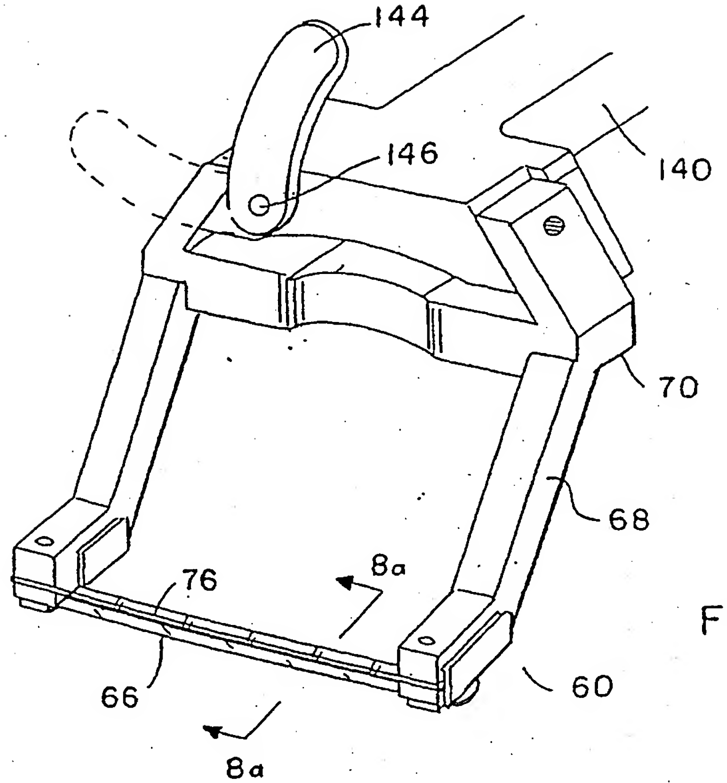


FIG. 9a

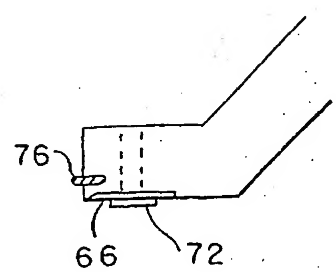
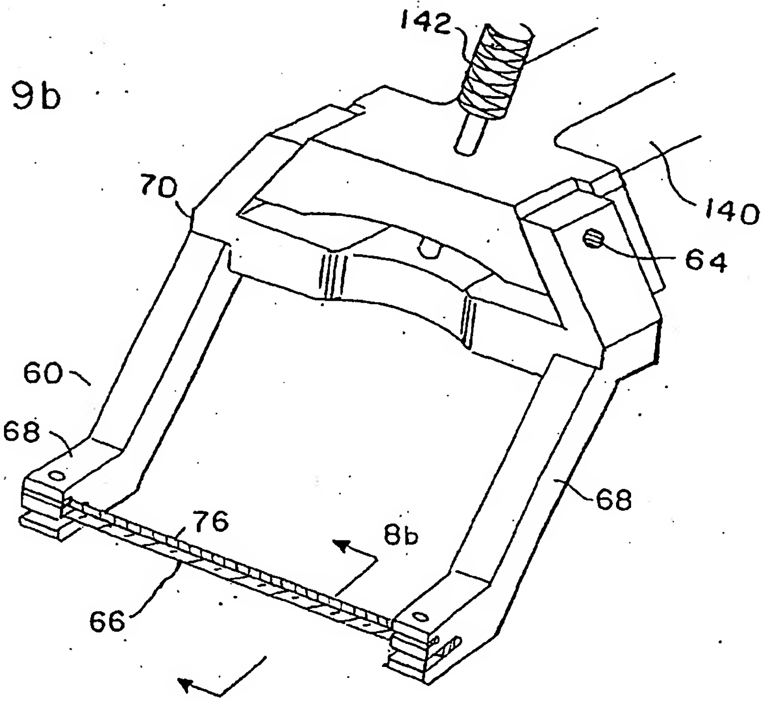


FIG. 8a

FIG.9b



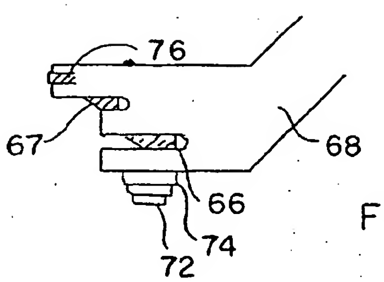


FIG.8c

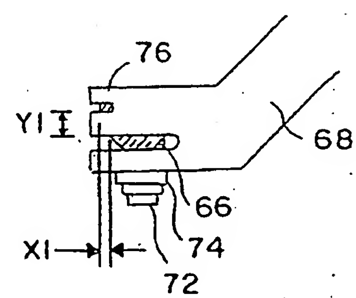
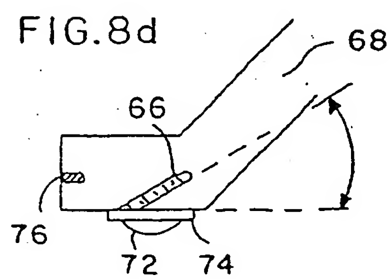


FIG.8d

FIG.8b



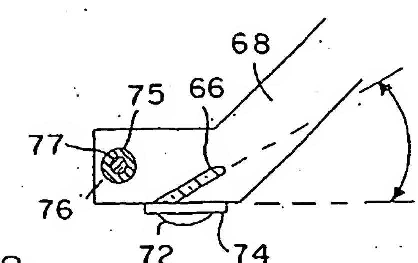


FIG.8e

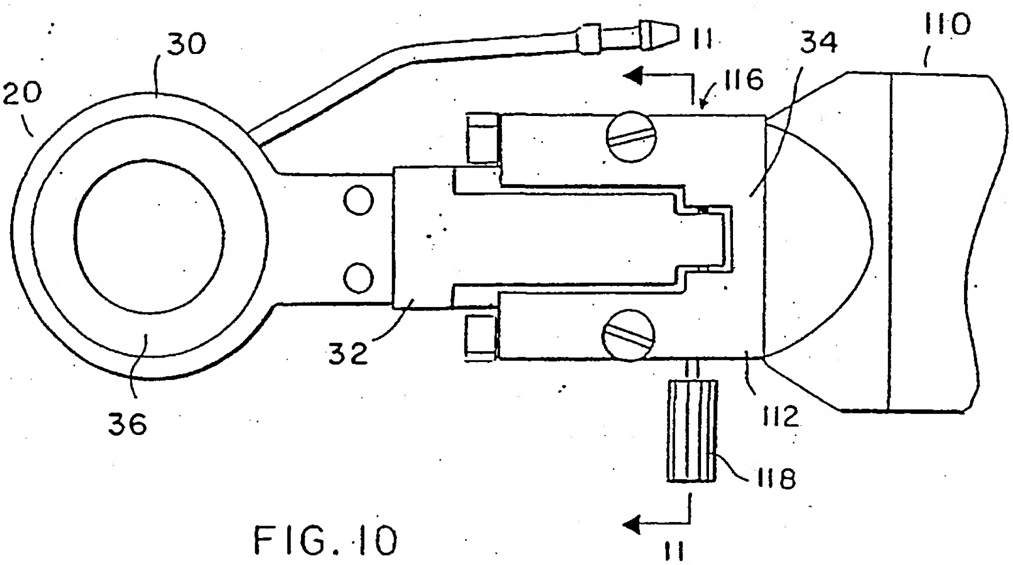


FIG. 10

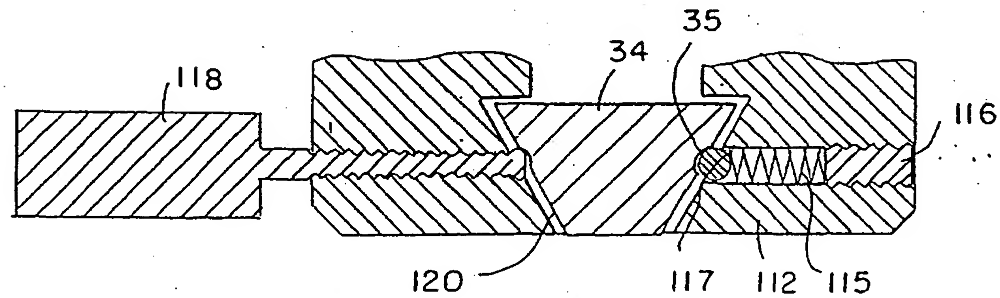


FIG. 11

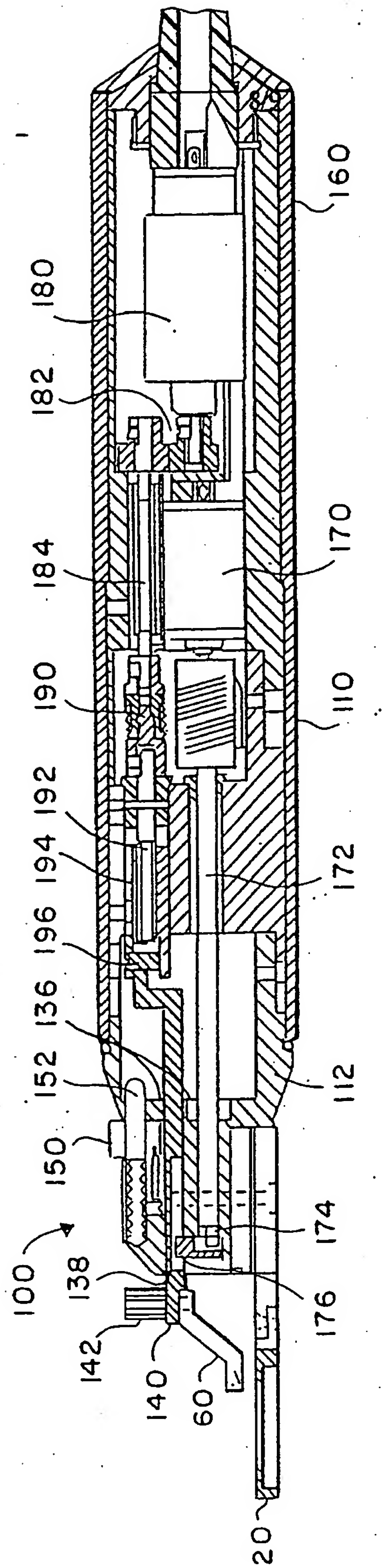

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FIG. 12

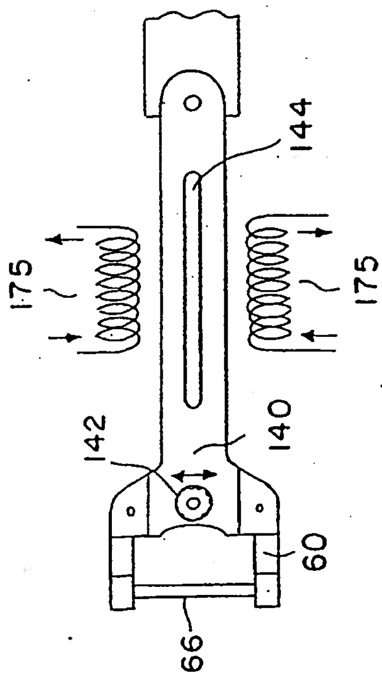
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FIG. 13

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/09363

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F9/013

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 989 272 A (BARRON MARK B ET AL) 23 November 1999 (1999-11-23) column 5, line 1 - line 30; figure 6	1-3
Y		4-6,20

Y	WO 00 09055 A (FEINGOLD VLADIMIR) 24 February 2000 (2000-02-24) page 9, paragraph 4 page 10, paragraph 4; figure 8I page 10, paragraph 3; figure 8H page 8, paragraph 4	4-6,20
A		1-3,7-10

A	WO 98 48747 A (HELLENKAMP JOHANN F) 5 November 1998 (1998-11-05) abstract; figure 2	9,10

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 November 2001	15/11/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 01/09363

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5989272	A	23-11-1999	NONE		
WO 0009055	A	24-02-2000	US	6083236 A	04-07-2000
			AU	5347799 A	06-03-2000
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			CN	1260701 T	19-07-2000
			CN	1260702 T	19-07-2000
			EP	0977532 A2	09-02-2000
			EP	1011564 A2	28-06-2000
			US	6007553 A	28-12-1999
			WO	9848747 A2	05-11-1998
			WO	9848748 A2	05-11-1998
			US	6132446 A	17-10-2000

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(30) Priority Data:
9902348-3 21 June 1999 (21.06.1999) SE

(71) Applicant (*for all designated States except US*): MICRO-MUSCLE AB [SE/SE]; Berzelius Science Park, S-582 25 Linköping (SE).

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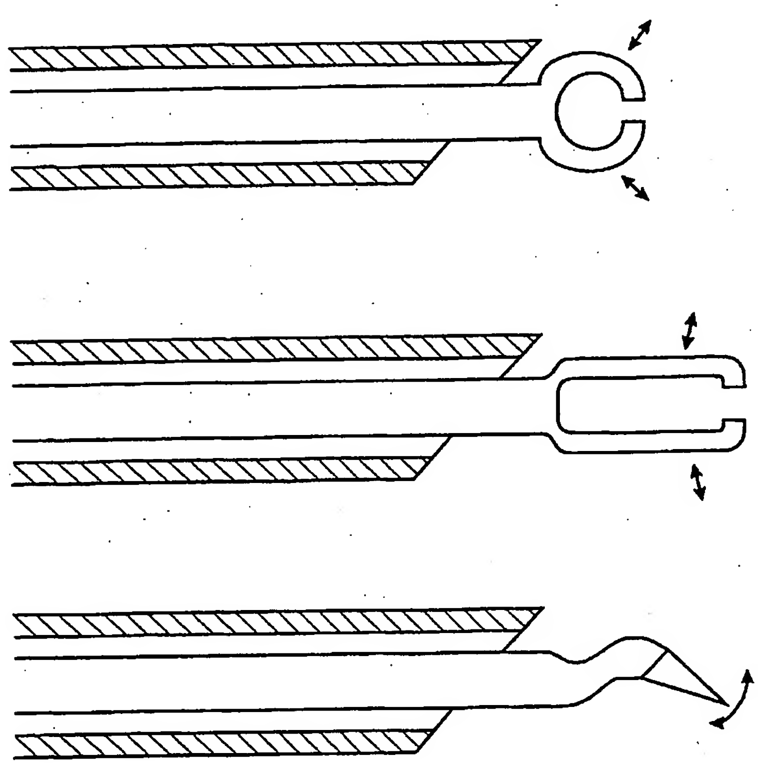
(74) Agent: BERGLUND, Erik; Berglunds Patentbyrå AB, Aspebråten, S-590 55 Sturefors (SE).

(81) Designated States (*national*): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European

[Continued on next page]

(54) Title: MICRO TOOLS



(57) Abstract: Tool arrays for biomedical surgery where the tools consist of layered polymer micromuscles arranged to induce geometrical changes and movements via an electrochemically induced change of volume in at least one polymer layer. The tool or tool arrays are mounted on a carrier having the form of a needle being inserted into a cannula/catheter through which the tools can be electrically actuated via external means to induce a mechanical movement to act upon biological structures.

WO 00/78222 A1

patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Micro tools

This invention concerns micro-surgical tools that can be delivered through or by a catheter or needle. These tools or micro-structures can be used to adapt, assemble, separate, fortify, dilate, close and hold biological structures inside the body during and after surgery. The tools may be stents, valves, clips, nets, knives, scissors, dilators, clamps, tweezers etc.

Introduction

The use of microstructures to assemble, fortify or dilate biological structures inside the body during and after surgery can help the surgeon in a number of ways. The operation of electrically actuated tools can help the surgeon to simultaneously position, operate manually, and observe. By positioning the tool by hand and separately operating it through external control (i.e. footswitch, voice control, other software-control) a much higher degree of precision is expected. In microsurgery, this is an especially desired advantage.

To be able to apply, beforehand or during an invasive procedure, a tool of a required size and geometry - designed for the purpose of cutting, drilling, holding, dilating, suturing, adapting or supporting - from tools that, for example, could be introduced through, placed inside or located at the end of a catheter or needle, is another desired function, requiring development of microactuators.

-The application of structures in or introduced through a catheter or needle is of particular interest at the application of tools, which are to be left at the site after insertion, and which have to execute their function for some limited time duration. The first example here is that of clips for surgery, sub-millimeter to millimeter structures, which would be used to hold two separated biological structures joined, for example during a healing period (Fig.1A - 1C).
-Another example is that of structures for controlling the flow through blood vessels. The simplest level is that of a clip used to prevent blood flow to a biological structure downstream in the blood flow. Such a clip, or series of clips, would be mounted and left to hold a firm grip

on the blood vessel and thus to prevent the flow of blood. In Figure 2 is shown a series of structures suitable for constricting blood vessels.

-The third example is at a somewhat more complex level with structures built in a geometry where they could be used inside or outside tube-like structures, as so called stents to dilate a stenotic area or to internally or externally fortify or join the structure(s) (Figure 5A and 5B). Stents are of particular interest since they are to be inserted inside the tube, then to be left there to expand a stenotic (examples: blood vessel, biliary duct) or to fortify a weak (examples: blood vessel with aneurysm, divided biliary duct) part of a tubular structure .

Arrays of fingers could be used to hold cylindrical objects, such as nerves and nerve fibers, or blood vessels. With the help of microactuators holding the structures (Fig. 3A - 3B), adjacent microstructures operating as neural sensing or activating electrodes, will enable recording signals from or activating nerves. This could be used as a synthetic neural connector, bridging a severed nerve or nerve fiber.

Elements with some temporary mechanical function could be inserted in membranes (Fig.4A - 4C). Insertion devices of this kind could be used for mounting a hole through a membrane such as commonly used in ear surgery for pressure equilibration. Making these as microdevices will much decrease the effort to place and remove the inserted devices and to keep them in place during the desired time period.

Clips, stents, finger arrays and insertion devices, once applied, could be resorbable or permanent. They could express various degrees of stimulation of cell growth on its surfaces, various degrees of anti-thrombotic activity as well as different antibiotic activities. They can also be carriers of various biochemical or biological components.

The necessary elements to accomplish these functions are the electrochemically activated micromuscles, built by micromachining thin metal and polymer layers (Elisabeth Smela, Olle Inganäs and Ingemar Lundström: "Controlled Folding of Micron-size Structures", Science **268** (1995) pp.1735-1738) or only polymer layers. These actuators can be produced in sizes from micrometers to centimeters, and operate well in biological fluids such as blood plasma, blood, buffer and urine. They are therefore suitable tools for micro invasive surgery inside the body.

The versatility of construction and the speed of response, as well as the force of these actuators render them as one of the best types of microactuators inside the body. An international patent covers one route of fabrication of such devices (A Elisabeth Smela, Olle Inganäs and Ingemar Lundström: "Methods for the fabrication of micromachined structures and micromachined structures manufactured using such methods ", Swedish patent application number SE 9500849-6, March 10, 1995 in succession also a PCT and international patent).

Prior art

The combination of microactuators and catheters are not well documented in the literature. A patent search reveals a few examples but none that describes the use of microactuators as tools housed inside a catheter; several examples of microactuators use to position a catheter are to be found in the following patents

US5771902	Micromachined actuators/sensors for intratubular positioning/steering
US5819749	Microvalve
WO9837816A1	Microfabricated therapeutic actuators
WO9739688A2	Method and apparatus for delivery of an appliance in a vessel
WO9739674A1	Spring based multi-purpose medical instrument
US5855565	Cardiovascular mechanically expanding catheter

Several mechanisms are suggested for the microactuators in these applications, found among shape memory alloys (including polymeric materials) and piezoelectric materials. The use of conjugated polymers in micromuscles is not documented for catheter tools. Our novelty and innovation therefore resides in the use of microactuators based on conjugated polymers being electrically operated and mounted in or on a catheter or needle, to be positioned with the help of the catheter, and then activating the microactuator structures carried on the needle. The microfabrication of such microactuators renders possible a number of geometries from 10 µm and larger, difficult to produce by mechanical production techniques. They may be produced by use of the method presented in patent A above and then mounted in or on the needle or catheter, or they might be produced by novel manufacturing methods. With the help of this invention, completely novel microsurgery tools are available.

The production of individually actuated tool arrays render little difficulty beyond that of producing the individual tool; we have to see that electrical contacts are supplied to actuate each microactuator separately. This can be done by wiring the single microactuator, to be used as the working electrode; the catheter is then used as the counterelectrode, and will be able to supply all the charge that we ever need to actuate all those microactuators. As wires may easily be produced in width down to 10 μm with photolithography or with soft lithography, we will be able to put at least 50 microactuators along the tool array located in/on a needle of 1 mm width, with the simple philosophy of putting down parallel conductor wires. Should we need more, more elaborate addressing schemes might be needed.

Should a necessity for three electrode systems be found in any of the applications, microfabricated reference electrodes or macrosize reference electrodes carried on the catheter housing offers a solution for this problem.

Should the tool arrays be collectively addressed, and the tool array is designed to set free the outermost clip on actuation of all the clips, we will need a mechanism of confining the movements of all but the outermost clip. This is done by assembling the clip array into a cylindrical housing, preferably the catheter, prior to insertion in the body. The cylindrical housing is now confining the motion of microactuators, which search in vain to expand the strong metal casing on operation. When the outermost clip C1 is actuated, the clip is opened; likewise is the next-to-the outermost clip C2 partially free to move as it is protruding outside the cylindrical housing. Therefore the partial opening of C2 sets C1 free, as well as opens it up for subsequent spontaneous closing on the site to be clipped.

Figure captions

Figure 1A - 1C shows clips and clip arrays, where the clips are mounted in sequence, and area confined by a cylindrical housing, and where the activation of the outer most clip C1, opening up the clip to join the open structure W1, and then being set free by the simultaneous operation of C2, so as to be left at the structure W1, holding the structures together.

Figure 2 shows tubular tweezers, tweezers and knifes, based on microactuators. The indicated movement is driven by microactuators properly mounted and designed.

Figure 3A - 3B shows a neural connector, where a number of small fingers coil around a cylindrical nerve to make a tight hold the nerve. Two separate nerves are here joined with the help of a common neural connector, which would be desired for accomplishing regrowth of the nerves. In addition, small electrodes can be fashioned along with the microfingers, and be used to sense or excite nerve signals.

Figure 4A - 4C. An insertion devise, for making a temporally permanent hole through a membrane. The devise is housed in a catheter/cannula/needle and is inserted through the membrane so as to make the devise form a hole through the membrane.

Figure 5A - 5B show a stent device.

CLAIMS

1. Tool arrays for biomedical surgery,
characterized in that
(i) the tools consist of layered polymer micromuscles arranged to induce geometrical changes and movements via an electrochemically induced change of volume in at least one polymer layer, and
(ii) the tool or tool arrays are mounted on a carrier having the form of a needle being inserted into a cannula/catheter through which the tools can be electrically actuated via external means to induce a mechanical movement to act upon biological structures.

2. Tool arrays according to claim 1, characterized in that the layered polymer consists of a single layered polymer.

3. Tool arrays according to claim 1, characterized in that the layered polymer consists of a bi-layered polymer.

4. Tool arrays according to claim 1, characterized in that the layered polymer consists of multilayered polymer and metal layers.

5. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to position a biological structure.

6. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to hold a biological structure.

7. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to cut a biological structure.

8. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to dilate a biological structure.

9. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to fortify a biological structure.

10. Tool arrays according to one or more of claims 1-4, characterized in that the mechanical movement is used to implant a biological structure.

11. Tool arrays according to one or more of claims 1-10, characterized in that a number of identical tools are located on a tool array extending along a length of the cannula, catheter or needle, and wherein the actuation of a tool closest to the exit of the catheter is arranged to release a tool from the tool array and is arranged to leave it at the point of exit of the catheter in order to mount the tool at/in some biological structure .

12. Tool arrays according to claim 11, characterized in that a number of identical tools are located on the tool array extending along the catheter or needle and where each tool is arranged to become individually actuated.

13. Tool arrays according to claim 11, characterized in that a number of non-identical tools are located on the tool array extending along the catheter or needle and where each tool is arranged to become individually actuated.

14. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a clip arranged to join biological tissues or tissue parts, and arranged to hold the said tissues or tissue parts to allow healing.

15. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is an expandable cylindrical object designed to be inserted, in a contracted state, into a biological tube, and arranged to become expanded to keep said tube in an expanded state or to join two or more biological tubes.

16. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a scissors.

17. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a knife, which is arranged on an actuator, being arranged for linear and/or angular movement.

18. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a sharp needle that is arranged on an actuator being arranged for linear and/or angular movement.

19. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a dilator.

20. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a clamp.

21. Tool arrays according to one or more of claims 1-13, characterized in that the individual tool is a tweezers.

22. Tool arrays according to one or more of claims 1-21, characterized in that the polymer micromuscles are built of layers, of which at least one is a conjugated polymer.

23. Tool arrays according to claim 22, characterized in that the conjugated polymer is selected from the group consisting of pyrrole, aniline, thiophene, para-phenylene, vinylene, and phenylene polymers and copolymers, including substituted forms of the different monomers.

24. Tool arrays according to claim 1, characterized in that the tool is built of bi-layered polymer, where the electrically activated volume change of said, at least one conjugated polymer is arranged to cause a bending of said bi-layer.

25. Tool arrays according to claim 1, characterized in that the tool is built of multilayered polymer, where the electrically activated volume change of said, at least one conjugated polymer is arranged to cause a bending of said multilayer.

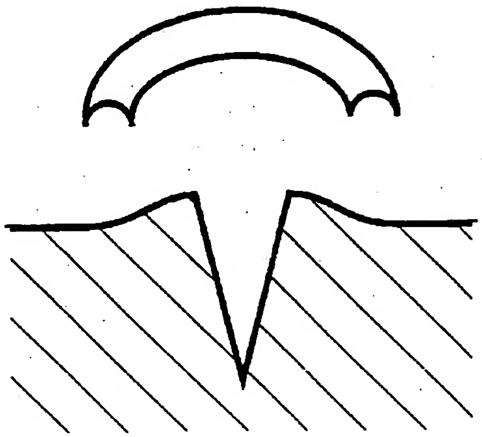


Fig 1a

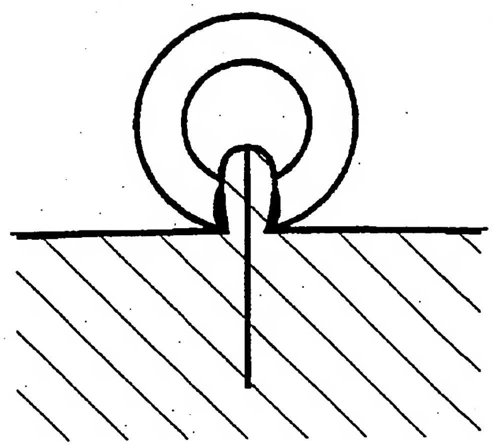


Fig 1b

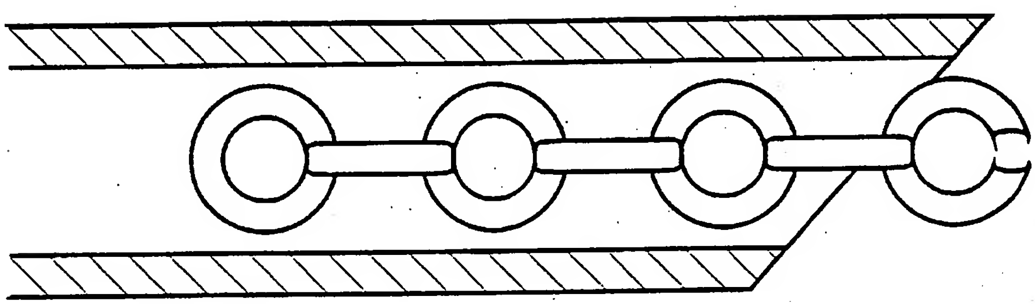


Fig 1c

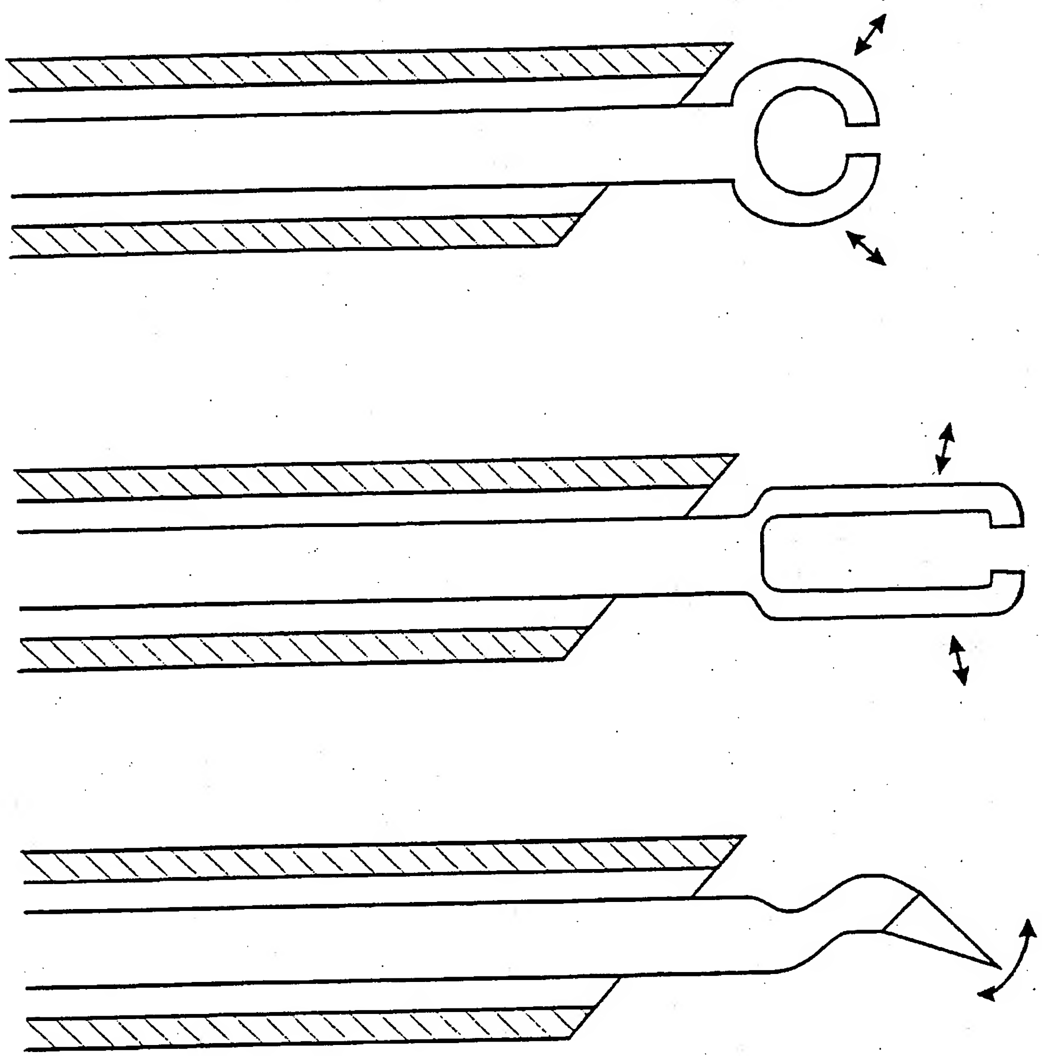


Fig 2

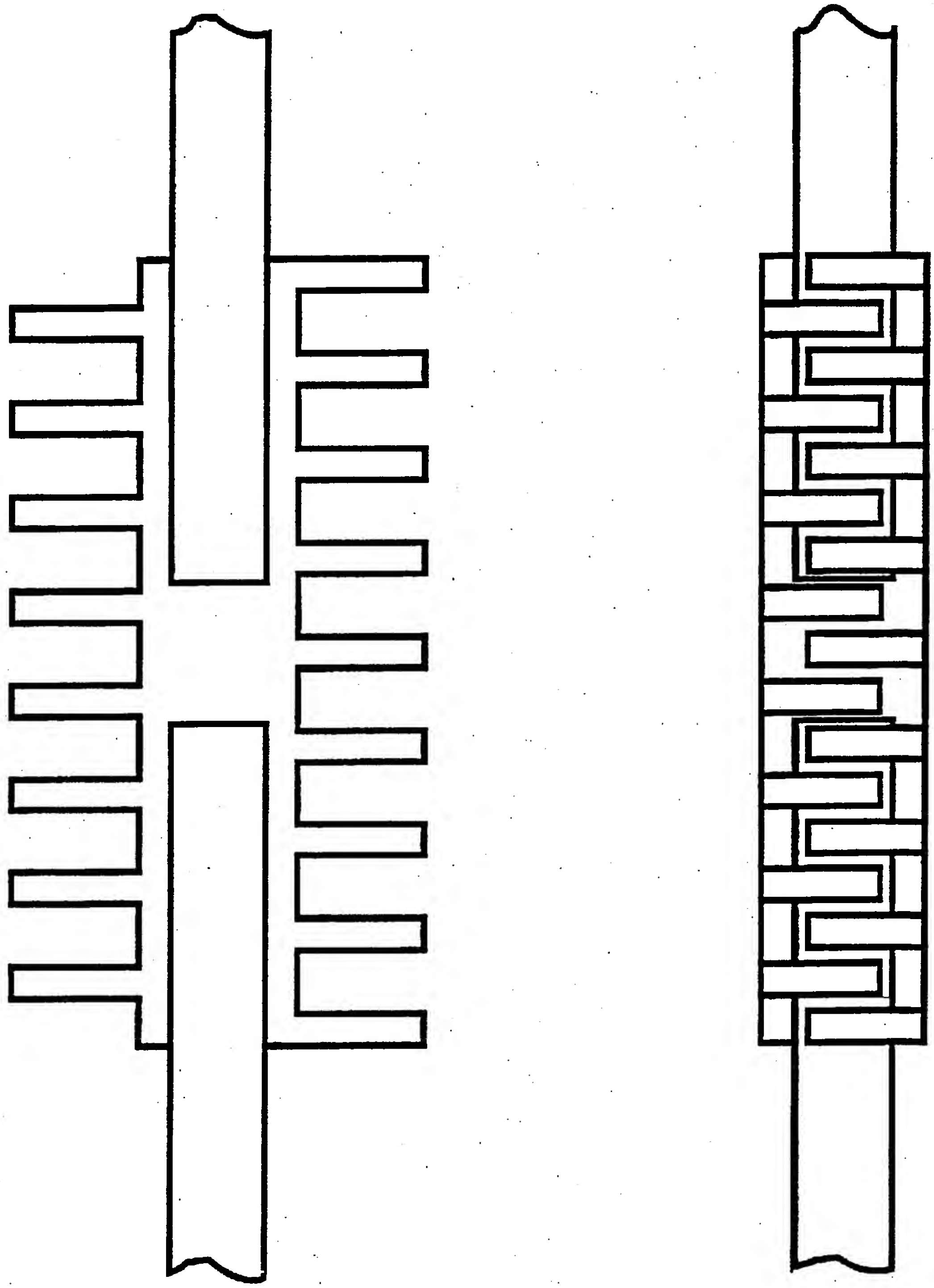


Fig 3a och 3b

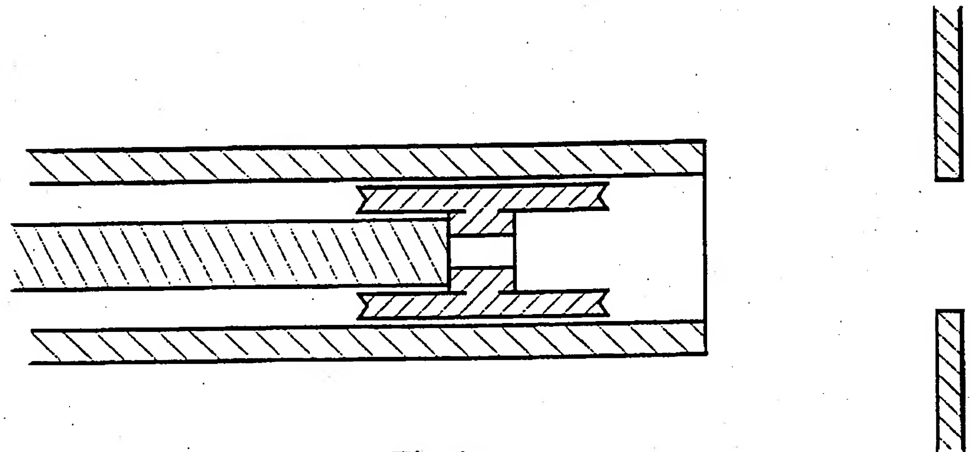


Fig 4a

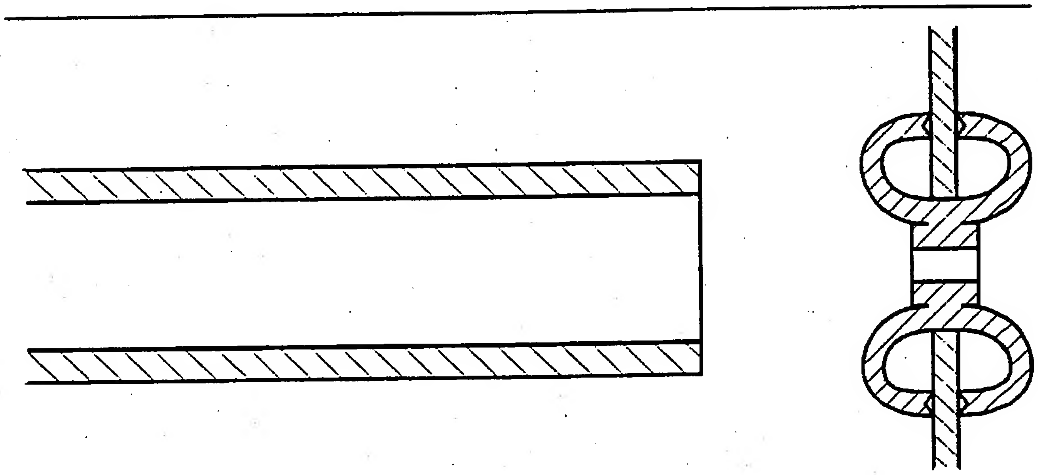


Fig 4b

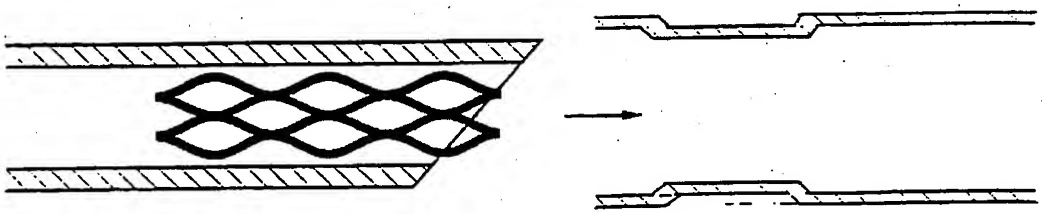


Fig 5a

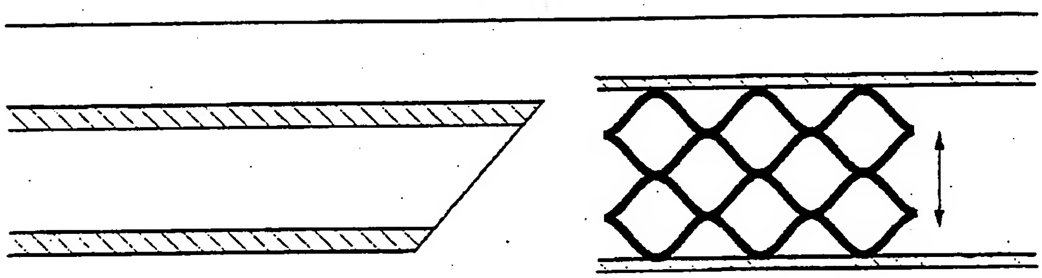


Fig 5b

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/01286

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 17/00, A61B 18/00 // A61L 27/00, A61L 31/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B, A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" erlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 Sept 2000	11-10-2000

Name and mailing address of the ISA/	Authorized officer
Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Anette Hall/Els Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/01286

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 5-10
because they relate to subject matter not required to be searched by this Authority, namely:
A method of treatment of the human or animal body by surgery or therapy (Rule 39.1(iv)).

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).:

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.